

Flexsafe® Pro Mixer 5 L | 10 L | 20 L

Modular, Scalable, and
Flexible for Small Volume
Mixing



Product Information

Mixing has many applications in a biomolecule manufacturing process. During process development or for small-scale batches, volumes of less than 20 L can be encountered. To facilitate scale-up to larger volumes, a single-use solution for mixing small volumes of powders or liquids with various viscosities is needed.

The Flexsafe® Pro Mixer 5 L | 10 L | 20 L is a single-use, benchtop mixer designed for small-scale mixing applications from 1 to 20 L. This mixer is engineered with powerful and low shear mixing capabilities, making it versatile for all process steps and applications, including upstream, downstream, and final formulation. The same mixing technology is available up to 3,000 L, simplifying scale-up to larger volumes.

Features and Benefits

- Powerful: Rapid powder dissolution or homogenization of highly viscous products
- Low shear: The levitating impeller supports gentle mixing for shear-sensitive products
- Modular: One Flexsafe® Pro Mixer Base Unit can hold the three available sizes of bag holders
- Scalable: Predictable mixing performances up to 1,000 L

Introduction

The Flexsafe® Pro Mixer is a single-use, benchtop mixer designed for small-scale mixing from 5 to 20 L. It is built on advanced Pro Mixer technology, engineered with a high-torque motor and low-shear mixing capabilities. This makes the solution versatile for all process stages and applications, including upstream, downstream, and final formulation.

The key features of the Flexsafe® Pro Mixer 5 L | 10 L | 20 L include:

Single-Use

The single-use mixing bag reduces contamination risk by eliminating the risk of cross-contamination between batches. It also saves time and resources by removing the need for cleaning and validation between batches. This feature enhances operational efficiency and compliance with regulatory requirements, making it an ideal choice for maintaining high hygiene standards in production.

Versatile

The Flexsafe® Pro Mixer is suitable for upstream processes such as media and buffer preparation, ensuring optimal conditions for cell culture and fermentation. It is also effective in downstream processes like clarification and harvest, improving product recovery and purity. Finally, the system is ideal for final formulation processes, ensuring consistent product quality and stability. This versatility supports research and development activities, providing a reliable tool for experimental and pilot-scale studies.

Powerful

Robust mixing ensures rapid dissolution of powders, enabling quick and efficient preparation of solutions. It provides effective homogenization of highly viscous products, ensuring uniform consistency and quality across the batch. This feature is ideal for applications requiring thorough mixing of complex formulations.

Low Shear

The Flexsafe® Pro Mixer features a levitating impeller designed to handle shear-sensitive products gently, minimizing damage. This preserves the integrity and functionality of sensitive components, making it suitable for mixing applications during the production of biologics and other fragile formulations. By reducing the risk of product degradation, Flexsafe® Pro Mixer maintains the efficacy of active ingredients, ensuring high-quality outcomes.

Scalable

The system delivers consistent mixing performance for volumes from 5 to 1,000 L, ensuring reliable results at different scales. This facilitates seamless scale-up to larger volumes, supporting both small-scale development and large-scale production. The ability to ensure reproducibility and scalability is critical for process development and commercial production, making the Flexsafe® Pro Mixer a valuable tool for manufacturing facilities.

Modular

The Flexsafe® Pro Mixer Base Unit is capable of accommodating three different sizes of bag holders, providing flexibility for various batch sizes. This allows for easy adaptation to changing production needs without the need for extensive equipment changes. This versatility also simplifies inventory management by using a single base unit for multiple applications, enhancing operational efficiency.

Compact

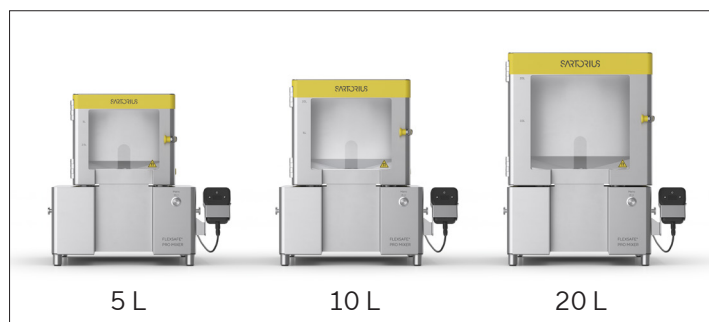
The Flexsafe® Pro Mixer is designed for small-scale mixing, making it ideal for laboratory and pilot-scale applications. It occupies minimal bench space, supporting the efficient use of the facility space. Its portability and ease of integration into existing workflows make it a convenient and practical solution for various mixing needs.

Relevant Applications

- Process development
- Clinical production
- Commercial production

Relevant Process Steps

- Media | buffer preparation
- Clarification | harvest
- Hold
- Drug substance and drug product formulation
- Fill and finish



Technical Specifications

The Flexsafe® Pro Mixer consists of three main components: the Flexsafe® Pro Mixer Base Unit, the Flexsafe® Pro Mixer Bag Holders and the Flexsafe® Pro Mixer bag.

Flexsafe® Pro Mixer Base Unit – Facility

Description	
Dimensions (W×L×H) [mm]	468×452×244
Weight [kg]	11.5
Material of construction	Stainless steel: AISI 304, 1.4301 Labels: PET PVC Gaskets: EPDM silicone
Surface finish	Bead blasted and passivated with a max. surface roughness of Ra ≤ 1.2
Operational footprint [mm]	867×671 with a minimum of 400×500
IP rating	54
Noise from operator position [dB]	70
Max humidity [%]	80
Operating Temperature [°C]	2 – 30
Impeller type	Saturn
Mixing speed [rpm]	0 – 750

Flexsafe® Pro Mixer Base Unit – Utilities

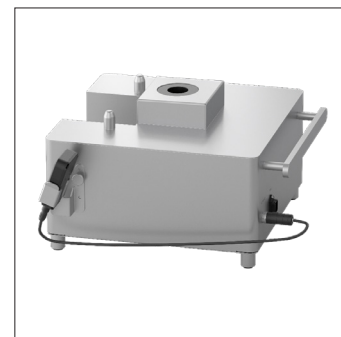
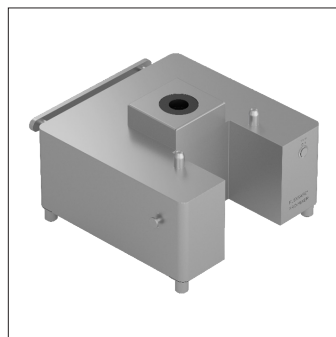
Description	
Electrical supply [V]	100 – 240
Mains input	1 ph. N PE
Frequency [Hz]	50 60
Max. power consumption [A]	0.84
Max. mains voltage fluct. [%]	± 10
Overvoltage cat. IEC60664-1	Type 2
Short circuit current rating [kA]	5
Interf. immunity IEC61326-1	B class
Motor power [W]	50

Flexsafe® Pro Mixer Base Unit – Control System

Description	
Control architecture	Speed control via external user panel: operation via buttons on user panel. Remote speed control signal and speed feedback signal: signal cable uses the same port as the user panel.
Power plug type	F, B, G, H, I, J, D/M, N,
Remote control connector	<ul style="list-style-type: none"> Connector: 15 pin "Series 915 TE Connectivity" 3 pins being occupied (analog, digital, RS485, ground, etc.), 2 pins open as power supply internally Analog In: Mixer Setpoint (4...20 mA) Analog out: Actual speed (0–10 V) Digital In1: Enable (5–24 V = active; 0V = not active) Digital In2: Reset (5–24 V = active; 0V = not active) Digital Out1: Status Digital Out2: Error

Flexsafe® Pro Mixer Base Unit – Electrical Safety

Description	
CE	Safety of electrical equipment, according to EN 61326-1 Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 1: General requirements (IEC 61326-1)
UL	UL 61010-1 UL 61010-2-010



Flexsafe® Pro Mixer Bag Holder 5 L | 10 L | 20 L

Description	Bag Holder 5 L	Bag Holder 10 L	Bag Holder 20 L
Dimensions (W×D×H) [mm]	275×299×240	315×339×276	377×401×341
Weight [kg]	6.5	8.6	12.6
Material of construction	Stainless steel AISI 304, 1.4301 Windows PC handle POM/PA gaskets EPDM		
Surface finish	Bead blasted and passivated with a max. surface roughness of Ra ≤ 1.2		
Nominal filling volume [L]	5	10	20
Max. overfilling volume [L]	5.5	11	22
Max. filling weight [kg]	7.15	13	26
Operating temperature [°C]	2–30	2–30	2–30



Flexsafe® Pro Mixer Tube Holder 5/8" and 7/16"

Description	Tube Holder 5/8"	Tube Holder 7/16"
Dimensions (W×D×H) [mm]	70×115×67	70×115×67
Weight [kg]	0.18	0.18
Material of construction	Stainless steel AISI 304	
Surface finish	Bead blasted and passivated with a max. surface roughness of Ra ≤ 1.2	

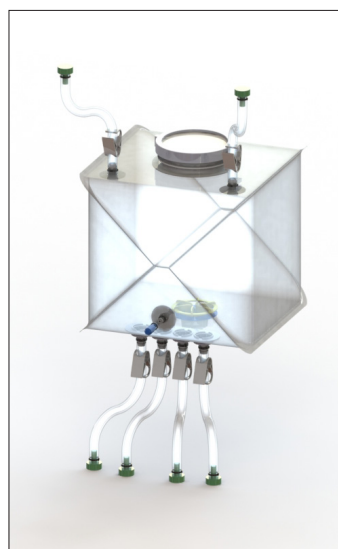
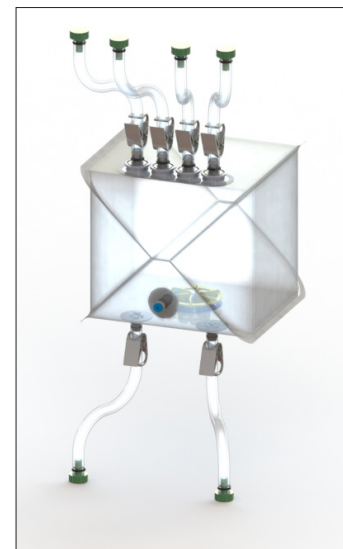
Flexsafe® Pro Mixer Lab Cart 650 mm

Description	
Dimensions (W×D×H) [mm]	578×1,149×1,021
Weight [kg]	36
Material of construction	Stainless steel AISI 304 (main); incl. PC, POM, PA, EPDM, iglidur J, PET, PVC, silicone elastomer; (electronic components excluded)
Surface finish	Bead blasted and passivated, Ra ≤ 1.2
Max humidity [%]	80
Ambient temperature [°C]	2–30

Single-Use Mixing Bags

Film	Flexsafe® S80 multi-layer film Contact layer: Linear low-density polyethylene (LLDPE) Core layer: Ethylene vinyl alcohol (EVOH) External layer: LLDPE 400 µm thickness
Bag shape	Cubical
Volumes	5 L 10 L 20 L
Bag Dimensions (H×L×W) [mm]	
5 L	175 × 200 × 200
10 L	208 × 233 × 233
20 L	263 × 288 × 288
Impeller position	Bottom centered
Impeller size material	76 mm (2.99") LDPE
Impeller maximum speed	750 rpm
Min – Max Volume*	
5 L	0.5 – 5.5 L
10 L	0.6 – 11 L
20 L	0.7 – 22 L
Top Ports	
5 L	4" opened top port up to 4 top lines if no 4" opened top port
10 L	4" opened top port up to 4 top ports if no 4" opened top port
20 L	4" opened top port + 2 top lines up to 4 top ports if no 4" opened top port
Front Port	
5 L 10 L 20 L	1 front line Thermowell
Bottom Ports	
5 L 10 L	2 bottom lines
20 L	Up to 4 bottom lines
Tubing material and diameter (ID×OD)	Tuflux® Silicone 3/8" × 5/8" 1/4" × 7/16" Tuflux® TPE 3/8" × 5/8" 1/4" × 7/16" 1/4" × 3/8"
Connectors	Aseptic and non-aseptic connectors
Operating temperature range	5 – 40 °C
Sterilization	Irradiation
Configurable	Yes

*This information is given as an indication of operating volumes.



Ordering Information

Hardware

Part Number	Volume [L]	Description	Type	Quantity
PRO-MIXER-SV	5 10 20	Flexsafe® Pro Mixer 5 L 10L 20L	Complete system	1
	5 10 20	Flexsafe® Pro Mixer Base Unit	Individual Components	1
	5	Flexsafe® Pro Mixer Bag Holder 5 L	Individual Components	1
	10	Flexsafe® Pro Mixer Bag Holder 10 L	Individual Components	1
	20	Flexsafe® Pro Mixer Bag Holder 20 L	Individual Components	1

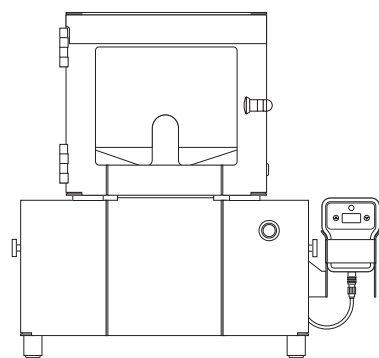
Single-Use Mixing Bag

Part Number	Volume [L]	Description	Quantity
FMS319774	5	Flexsafe® Cubical for Pro Mixer 5 L (Pwd Port)	1
FMS319775	10	Flexsafe® Cubical for Pro Mixer 10 L (Pwd Port)	1
FMS319776	20	Flexsafe® Cubical for Pro Mixer 20 L (Pwd Port)	1
FMS319777	5	Flexsafe® Cubical for Pro Mixer 5 L	1
FMS319778	10	Flexsafe® Cubical for Pro Mixer 10 L	1
FMS319779	20	Flexsafe® Cubical for Pro Mixer 20 L	1

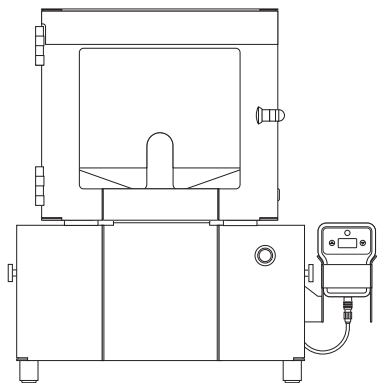
Peripherals and Accessories

Part Number	Volume [L]	Description	Quantity
FXC301595	5 10 20	Flexsafe® Pro Mixer Tube Holder $\frac{5}{8}$ "	1
FXC301596	5 10 20	Flexsafe® Pro Mixer Tube Holder $\frac{7}{8}$ "	1
FXC301598	5 10 20	Flexsafe® Pro Mixer Lab Cart 650 mm	1

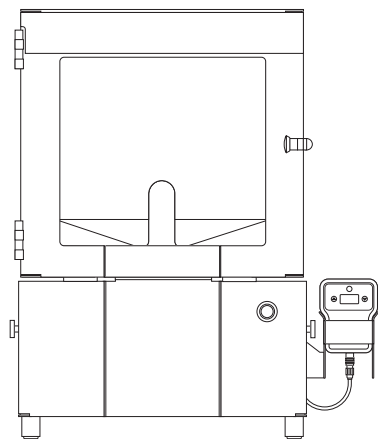
Technical Specification



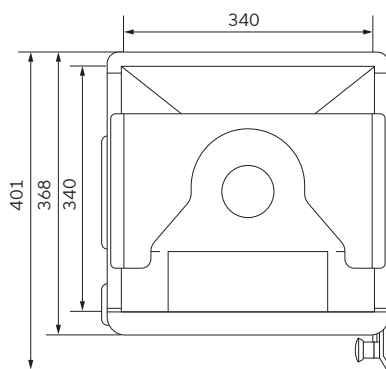
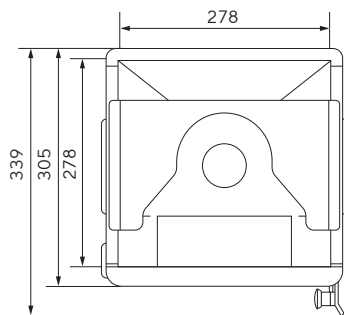
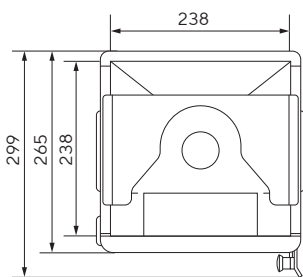
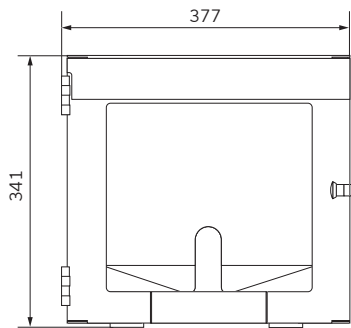
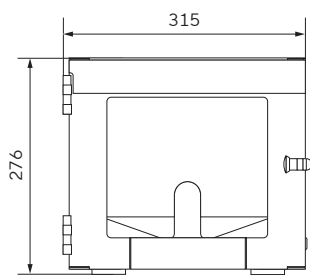
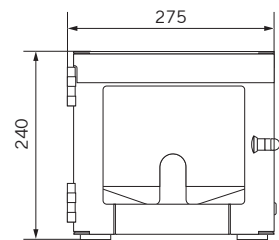
Flexsafe® Pro Mixer Bag Holder 5 L



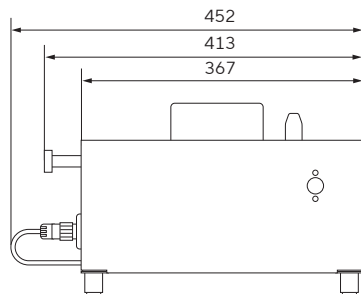
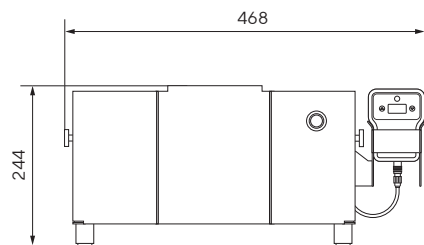
Flexsafe® Pro Mixer Bag Holder 10 L



Flexsafe® Pro Mixer Bag Holder 20 L



Flexsafe® Pro Mixer Base Unit



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