

LevMixer™ gen V

SINGLE-USE MIXING SYSTEMS

The LevMixer™ drive unit gen V and the LevMixer and magnetic mixer tanks gen V combine to create a single-use mixing system, designed to support various applications in biopharmaceutical manufacturing with the tried-and-tested LevMixer technology and additional features (Fig 1). With a mixing tank range of 50 to 1600 L, this scalable single-use mixing system has proven heating and cooling capability. It features a robust design, improved cleanability, a built-in automation panel on the tank to monitor critical process parameters, and a drive unit that provides ethernet communication and stand-alone operation mode.

The LevMixer single-use mixing system gen V includes an interchangeable superconducting drive unit and proprietary levitating impeller-based single-use biocontainer fitted into stainless steel (SS) mixing tanks. Once charged and coupled with the tanks and a biocontainer, the superconducting drive unit induces levitation and rotation of the impeller (Fig 2), resulting in effective mixing action inside a closed mixing system. Coupling the impeller with the drive motor requires no dynamic seals or shaft penetration inside the single-use system. The drive motor is enclosed on a portable cart that can be easily connected and disconnected to the mixing system, enabling its use with multiple single-use systems of various sizes.

The system includes a real-time reading of the impeller speed, with process monitoring and alert capability in case of process disruptions. End users can access detailed, real-time activity reports to monitor the mixer on site or remotely.

The system utilizes disposable mixing biocontainers made from Allegro™ film. It is animal-derived component-free (ADCF) and complies fully with USP Class VI requirements. The LevMixer drive unit gen V is backward compatible with all LevMixer and magnetic mixer tanks. It enables mixing across the bioprocess workflow steps with a simple drive unit change and the corresponding consumable and mixing tank.



Fig 1. LevMixer drive unit gen V coupled with the 200 L LevMixer and magnetic mixer tank gen V.



Fig 2. LevMixer drive unit gen V with a levitating impeller blade.

Features and benefits

- Scalable volume from 16 to 1600 L, depending on the tank size (50 L is the smallest tank size).
- The LevMixer drive unit gen V is backward compatible with all LevMixer and magnetic mixer tanks.
- Integrated control cabinet and an updated tank design minimize the footprint of the tank.
- Superconductive levitation technology provides low-shear, low-particulate mixing.
- No shaft, seals, or bearings inside the single-use mixer system: less mechanical shear.
- Ideal for sensitive product mixing.
- The tank and drive unit are designed with cleanability in mind – smoother, more curved frames, with less crevices, and hygienically-designed load cells.

Recommended applications

- Fill and finish/final formulation
- Product homogenization
- Suspension/re-suspension
- Media and buffer preparation
- Gene therapy
- mRNA and new modalities

Contact our application experts for help evaluating your options if your intended use is not listed.

System overview

Principle of operation

The LevMixer system technology is based on non-contact magnetic coupling between conventional permanent magnets in the impeller and superconducting material in the drive (Fig 3). Superconducting material can trap the magnetic field generated by the permanent magnets and 'lock the magnetic field in memory' in an equilibrium position. The trapped magnetic field behaves like mechanical springs; if the magnet is moved up, down, or sideways by outside forces (e.g., gravity or angular torque), it will tend to be pulled back to an equilibrium position. The nature of the magnet-superconductor interaction ties the two bodies together, resulting in a stable magnetic coupling with finite equilibrium separation.

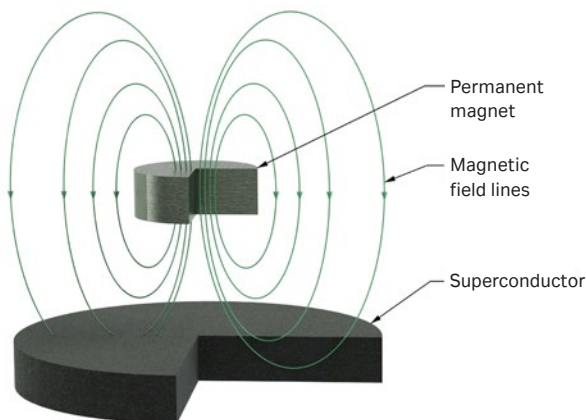


Fig 3. Principle of operation for LevMixer impeller.

Single-use system

Single-use biocontainers

LevMixer single-use biocontainers include a bottom-mounted single-use impeller that levitates during operation. The impeller is coupled with a mobile superconductive drive unit, which allows it to rotate while levitating. LevMixer biocontainer bags are made from Allegro bioprocess film, which is ADCF and complies fully with USP Class VI requirements.

The biocontainer is designed for open processing with universal sanitary flange connections. This design has two main inlets and two smaller inlets on the top face, a 101.6 mm (4 in.) powder port, a thermowell, two sensor ports, and a bottom drain. This universal design is well suited for sensing, pH adjustment, buffer prep, and media prep applications.

All generations of LevMixer single-use biocontainers (for cubical tanks) can also be used with the LevMixer drive unit gen V and the LevMixer and magnetic mixer tanks gen V.

Minimum volume criteria

Minimum volumes for each tank size are listed in technical specifications: mixing tanks. Figure 4 provides a visual reference for minimum working volumes inside the biocontainer.

Minimum mixing volume is the volume required to completely immerse the impeller blades at rest, and is the minimum volume for effective liquid-liquid mixing. Note that for challenging applications such as some liquid-solid mixing, this volume may not be sufficient.

Minimum sensing volume is the lowest volume that allows for the sensor probe to be fully immersed.

Minimum agitation volume is the lowest feasible working volume of the mixer, defined as the volume required to reach the lowest parts of the impeller blades at rest.

For further information, see technical specifications: mixing tanks.

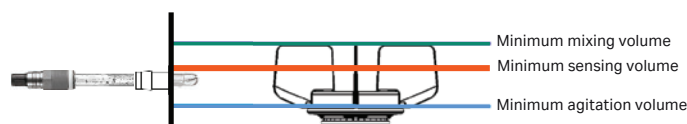


Fig 4. Visualization of minimum working volumes.

Drive unit

The system includes a superconducting drive unit (Fig 5) that works with all generations of the mixing tanks.



Fig 5. LevMixer drive unit gen V.

Key features

- The drive unit features a smooth, curved frame and reduces the number of exposed cables.
- Optimized hardware design for more efficient drive-unit docking.
- Improved automation system for integration into a Delta V distributed control system (DCS) system via OPC UA communication.

Docking system

The drive motor is enclosed on a portable cart that can be easily disconnected from the single-use system and reconnected to another single-use system. One drive unit allows mixing in multiple single-use mixing systems of various sizes.

Drive unit controller

The controller (Fig 6) is an onboard touchscreen and human-machine interface (HMI), which provides a real-time reading of the impeller blade speed and process monitoring/alert capability in case of process disruptions. Users may access a detailed activity report during operation. This information can also be exported to external systems for remote monitoring and control.



Fig 6. Control screen (HMI) of the LevMixer drive unit gen V.

Impeller

Once coupled with the single-use system, the superconducting drive unit induces levitation and rotation of the impeller (Fig 7). Coupling the impeller with the drive motor requires no dynamic seals or shaft penetration inside the single-use system, so the mixing system remains closed. To improve quality, a new impeller guard component has been developed to increase the protection of the biocontainer film of LevMixer and magnetic mixer systems. This guard acts as a protection ring in the updated LevMixer single-use biocontainers.



Fig 7. Impeller.

Toolbox

Several accessories and spare parts are available for process-specific needs (Fig 8). See ordering information for additional details.



Part	Description
1	Toolbox
2	Four magnet impeller with shield (blue)
3	Magnetic clamp
4	Hex key 4
5	Clip for 25.4 mm (1 in.) drain valve
6	Centering aligner
7	Power cord to connect the drive unit to the tank
8	Four magnet charger with shield (blue)
9	Ethernet cable

Fig 8. LevMixer drive unit gen V toolbox accessories.

Mixing tanks

The mixing tanks are vessels or totes mounted onto a frame where the single-use biocontainers are installed (Fig 9). The tanks are available in seven volumes from 50 to 1600 L nominal capacity and feature load cells and a full thermal jacket (sidewalls and bottom). American Society of Mechanical Engineers (ASME) certification is available for North American customers. Mixing tanks are supplied separately from the drive unit.



Fig 9. A 1600 L LevMixer and magnetic mixer tank with a biocontainer installed and a LevMixer drive unit gen V attached.

Electrical cabinet

The electrical cabinet is integrated into the design of the mixing tank (Fig 10) and provides the equipment necessary to monitor the biocontainer weight, pH, conductivity, and temperature. It contains the electrical connections for pH and conductivity sensing probes, temperature sensor, and communication ports to extract and log data for process monitoring requirements.



Fig 10. A 200 L LevMixer and magnetic mixer tank with the integrated electrical cabinet, and the LevMixer drive unit gen V.

Technical specifications: drive unit

Category	Parameter	Specification
Facility	Dimensions (W × L × H)	Configuration in position 1* 39 × 122 × 105 cm 15 × 48 × 41 in.
	Weight	63 kg (139 lb)
	Materials of construction	Controller, cart, and mixer enclosure: 304 stainless steel Wheels: polyurethane
	Surface finish Ra	≤ 1.2 μm (47 μin)
	Enclosure rating	Control box: IP54 Drive unit enclosure: IP23
	Noise (at operator position)	55 dB
	Maximum humidity	85%, avoid condensation
	Ambient temperature	4°C to 40°C
Utilities	Electrical supply	Single phase 100 V-230 V AC, 50/60 Hz
	Power cord/plug type, ordered separately	US: NEMA 5-15 EU: CEE 7/7 UK: BS 1363-1:2016+A1:2018 AU: AS/NZS 3112:2017 CH: IEC 60884-1 (ed.3):2002+A1:06+A2:13
	Amperage	110 V 2.5 A; 230 V 1.5 A
	Motor power	0.10 kW
Control system	Control architecture	Touchscreen PLC
	Remote control	Ethernet communication (OPC UA, DeltaV software)
	Speed range (dry conditions) [†]	20 to 210 rpm
Electrical/safety	CE	EN60204-1: 2016 Machinery Directive EN61000-6-4:2007(EN55011:2016) EN61000-6-2:2005 EMC Directive
	UL	UL 61010-1: 2012 Ed.3 and 61010-2-051: 2015 Ed.3 Standard for Safety Electrical Equipment for Measurement and Control
Environmental conditions	Indoor or outdoor use	Indoor
	Altitude	Maximum 2000 m above sea level
	Operating temperature	4°C to 40°C
	Operating relative humidity	20% to 85% (without condensation)
	Mains supply voltage fluctuations	± 10%
	Overvoltage category	II
	Wet location	No
	Pollution degree of intended environment	2
	Storage temperature	-25°C to 55°C
	Storage humidity	< 70% RH (relative humidity)
	Noise level	< 70 dB

* The drive unit can be used in four configurations. Each configuration allows connection to different tank sizes. See the instruction manual for full details.

[†] Speed range tested in dry conditions. Range may vary in fluids depending on fluid viscosity and density.

Note that the drive unit gen V (LMG501) can be used with the LevMixer and magnetic mixer tanks gen V, and all previous generations of the LevMixer and magnetic mixer tanks.

Technical specifications: mixing tanks

Category	Parameter	Specification
Facility	Materials of construction	304 stainless steel Wheels: polyamide
	Surface finish Ra	Brush polished: $\leq 0.89 \mu\text{m}$ (35 μin)
Load cells	Type	50 to 1600 L: Mettler Toledo SLB515
	Quantity	3 for 50 to 1000 L 4 for 1600 L
	Range	Nominal volume of size container
	Accuracy	0.3% on nominal volume for 50 and 100 L 0.1% on nominal volume for 200, 400, 650, 1000, and 1600 L
	Indicator type	Mettler Toledo IND 360
	Indicator output	Industrial ethernet
Utilities	Electrical supply	Single phase 100 V-230 V AC, 50/60 Hz
	Cable 6 m (20 ft); order separately	US: NEMA 5-15 EU: CEE 7/7 UK: BS 1363-1:2016+A1:2018 AU: AS/NZS 3112:2017 CH: IEC 60884-1 (ed.3):2002+A1:06+A2:13
	Amperage	115 V 2.25 A; 230 V 1.3 A
Control system	Control architecture	HMI touchscreen and PLC
	Remote control	Ethernet communication (OPC UA, DeltaV control software)
Jacket	Type	Dimple jacket
	Insulation	Mineral wool
	Temperature range	-5°C to 60°C
	Jacket connections	1½ in. sanitary connection
	Jacket pressure rating	Maximum 6.2 barg/90 psig
	Regulatory compliance	Directive 2014/68/EU
	Regulatory compliance ASME variant	ASME BPVC Sect VIII Div.1 Code Certification Stamp: U
Electrical/Safety	CE	EN60204-1: 2016 Machinery Directive EN61000-6-4:2007 (EN55011:2016) EN61000-6-2:2005 EMC Directive
	UL	UL 61010-1: 2012 Ed.3 and 61010-2-051: 2015 Ed.3 Standard for Safety Electrical Equipment for Measurement and Control
Environmental conditions	Indoor or outdoor use	Indoor
	Altitude	Maximum 2000 m above sea level
	Operating temperature	4°C to 40°C
	Operating relative humidity	20% to 85% (without condensation)
	Mains supply voltage fluctuations	$\pm 10\%$
	Overvoltage category	II
	Wet location	No
	Pollution degree of intended environment	2
	Storage temperature	-25°C to 55°C
	Storage humidity	< 70% RH
	Noise level	< 70 dB
50 L mixing tank: operating volumes	Maximum	50 L
	Agitation (minimum)	7 L
	Mixing (minimum)	16 L
	Sensing (minimum)	13 L
	Weight (product code LM50BCTE)	185 kg (408 lb)
	Dimensions	77.0 × 106.8 × 134.5 cm (30.3 × 42.0 × 53.0 in.)

Category	Parameter	Specification
100 L mixing tank: operating volumes	Maximum	100 L
	Agitation (minimum)	8 L
	Mixing (minimum)	22 L
	Sensing (minimum)	17 L
	Weight (product code LM100BCTE)	220 kg (485 lb)
	Dimensions	77.0 × 110.8 × 134.5 cm (30.3 × 43.6 × 53.0 in.)
200 L mixing tank: operating volumes	Maximum	200 L
	Agitation (minimum)	12 L
	Mixing (minimum)	30 L
	Sensing (minimum)	25 L
	Weight (product code LM200BCTE)	305 kg (672 lb)
	Dimensions	79.0 × 116.8 × 134.5 cm (31.1 × 46.0 × 53.0 in.)
400 L mixing tank: operating volumes	Maximum	400 L
	Agitation (minimum)	19 L
	Mixing (minimum)	56 L
	Sensing (minimum)	40 L
	Weight (product code LM400BCTE)	375 kg (827 lb)
	Dimensions	96.2 × 142.2 × 134.5 cm (37.9 × 56.0 × 53.0 in.)
650 L mixing tank: operating volume	Maximum	650 L
	Minimum agitation	25 L
	Minimum mixing	76 L
	Minimum sensing	55 L
	Weight (product code LM650BCTE)	475 kg (1047 lb)
	Dimensions	109.5 × 155.8 × 146.6 cm (43.1 × 61.3 × 57.7 in.)
1000 L mixing tank: operating volumes	Maximum	1000 L
	Agitation (minimum)	33 L
	Mixing (minimum)	100 L
	Sensing (minimum)	73 L
	Weight (product code LM1000BCTE)	590 kg (1300 lb)
	Dimensions	123.2 × 169.5 × 161.7 cm (48.5 × 66.7 × 63.7 in.)
1600 L mixing tank: operating volumes	Maximum	1600 L
	Agitation (minimum)	41 L
	Mixing (minimum)	133 L
	Sensing (minimum)	65 L
	Weight (product code LM1600BCTE)	750 kg (1653 lb)
	Dimensions	129.6 × 186.3 × 180.4 cm (51 × 73.3 × 71 in.)

Note that the LevMixer and magnetic mixer tanks gen V can be paired with all previous LevMixer and magnetic mixer drive units, apart from the 1600 L tank. LM1600BCTE can only be used with the LevMixer drive unit gen V, and the corresponding single-use biocontainer.

Ordering information

Type	Description	Product code
Drive unit	LevMixer drive unit gen V	LMG501
Spare parts and accessories for LevMixer drive unit gen V		
Power cords	USA (order separately)	LT-SVSP365
	Europe (order separately)	LT-SVSP366
	AU (order separately)	LT-SVSP367
	CH (order separately)	LT-SVSP368
	UK (order separately)	LT-SVSP369
	CN (order separately)	LT-SVSP480
Toolbox	(Comes with the LMG501)	PHB0055397

LevMixer and magnetic mixer tanks gen V

Stainless steel cubical container with automation, bottom-jacketed with load cells

50 L, SS cubical container, bottom-jacketed, with load cells and automation	LM50BCTE-B4N
100 L, SS cubical container, bottom-jacketed, with load cells and automation	LM100BCTE-B4N
200 L, SS cubical container, bottom-jacketed, with load cells and automation	LM200BCTE-B4N
400 L, SS cubical container, bottom-jacketed, with load cells and automation	LM400BCTE-B4N
650 L, SS cubical container, bottom-jacketed, with load cells and automation	LM650BCTE-B4N
1000 L, SS cubical container, bottom-jacketed, with load cells and automation	LM1000BCTE-B4N
1600 L, SS cubical container, bottom-jacketed, with load cells and automation	LM1600BCTE-B4N

Stainless steel cubical container with automation, bottom-jacketed (ASME certified) with load cells

50 L, SS cubical container, jacketed (ASME), with load cells and automation	LM50BCTE-B4A
100 L, SS cubical container, jacketed (ASME), with load cells and automation	LM100BCTE-B4A
200 L, SS cubical container, jacketed (ASME), with load cells and automation	LM200BCTE-B4A
400 L, SS cubical container, jacketed (ASME), with load cells and automation	LM400BCTE-B4A
650 L, SS cubical container, jacketed (ASME), with load cells and automation	LM650BCTE-B4A
1000 L, SS cubical container, jacketed (ASME), with load cells and automation	LM1000BCTE-B4A
1600 L, SS cubical container, jacketed (ASME), with load cells and automation	LM1600BCTE-B4A

Note that all previous versions of LevMixer and magnetic mixer drive units can be used with the 50 to 1000 L LevMixer and magnetic mixer tanks gen V.

Single-use biocontainers

50 L LevMixer biocontainer gen V	6403-2191T
100 L LevMixer biocontainer gen V	6403-2191S
200 L LevMixer biocontainer gen V	6403-2191R
400 L LevMixer biocontainer gen V	6403-2191Q
650 L LevMixer biocontainer gen V	6403-2191P
1000 L LevMixer biocontainer gen V	6403-2191N
1600 L LevMixer biocontainer gen V	6403-1857R

Previous-generation LevMixer single-use biocontainers can also be used with the LevMixer drive unit gen V and the LevMixer and magnetic mixer tanks gen V. Magnetic mixer single-use biocontainers can also be used with magnetic mixer drive units and tanks gen V. The range is backward compatible, apart from the 1600 L LevMixer single-use biocontainer, which can only be used with the drive unit gen V and the 1600 L mixing tanks gen V.

Spare parts for mixing tanks

Description	Product code
Clip for 1 in. EZD valve*	LT-SVSP312
Drive biocontainer interface (recommended spare part)	LT-DBBI009
O-ring for interface (recommended spare part)	LT-DBBI004
Magnetic clamp type 2 (recommended spare part)	LT-SVSP309
Centering aligner (recommended spare part)*	LT-SVSP305

* Required if multiple containers are offered with one drive unit.

Accessories for mixing tanks

Pressure relief valve (PRV)	PHB0050729
Filter holder	PHB0055430
Powder bag lift medium/large	LGRMXPBSM/ LGRMXPBSL
Powder bag lift hook	PHB0057710
Mastermover hook 50, 100, and 200 L	PHB0052770
Powder port support	PHB0057590

Reusable sensors

These pH and conductivity sensors need to be ordered separately.

Hamilton EasyFerm Bio HB Arc 120 pH probe, 120 mm length	XMPROBE- PH-120
Hamilton Conducell 4USF Arc 120 conductivity probe, 120 mm length	XMPROBE- COND-120

Service Information

Regular service and maintenance is necessary to maintain optimal condition and to extend the operational lifetime of the components.

Service and preventive maintenance work must be performed according to Cytiva recommendations, and according to the maintenance instructions of the component manufacturers.

Contact your Cytiva representative for information about the frequency of service requirements to suit individual process needs and for details of the Cytiva service agreement options that are available.

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