LevMixer™

MIXING SYSTEMS

The LevMixer™ system is specifically designed to fulfil the needs for very shear sensitive mixing in the bioprocess industry (for instance for mixing steps for the mRNA process or final fill and finish steps). This system is a mobile, flexible mixing system that allows efficient and reproducible single-use mixing up to 1000 L. The LevMixer hardware has been engineered for use with single-use systems (SUS) in current good manufacturing practice (cGMP) certified cleanrooms.

The LevMixer system consists of an interchangeable superconducting drive unit and proprietary levitating impeller-based single-use mixing system fitted into either plastic tanks located on a trolley or stainless steel (SS) tanks. Once charged and coupled with the SUS, the superconducting drive unit induces levitation and rotation of the impeller (Figure 2) resulting in effective mixing action inside a closed mixing system. Coupling of the impeller with the drive motor requires no dynamic seals or shaft penetration inside the SUS. The drive motor is enclosed on a portable cart that can be easily disconnected from the SUS and reconnected to another mixing system, allowing mixing in multiple single-use mixing systems of various sizes with a single drive unit.

The LevMixer system includes a real-time reading of the impeller speed and a process monitoring/alert capability. In case of any process disruption, the user is alerted. End users may access a detailed activity report during on-going applications to monitor the mixer either on site, or remotely from a different location.

The LevMixer system utilizes disposable mixing biocontainers made from Allegro™ film. It is animal derived component free (ADCF) and complies fully with USP Class VI requirements. Both Magnetic Mixer systems and LevMixer systems use the same hardware, providing a mixer for buffer and media to the final filling process steps with a simple drive unit change and the corresponding consumable.

Fig 1. LevMixer system.

LevMixer systems offer the following features and benefits:

- Scaling from 7 to 1000 L
- Interchangeable with Magnetic Mixer system technology (same containers)
- Superconductive levitation technology
- No shaft, seals or bearings inside the single-use mixer system: no mechanical shear
- Sensitive product mixing
- Drive unit flexibility (fits all container sizes)
- Data transfer and control options via Allegro MVP single-use system or control box

Applications

- Downstream applications
- Fill and finish
- Gene therapy
- mRNA and new modalities

Technical specifications

Parameter	Single-use impeller
Type	Radial flow
Number of blades	Four (4)
Material	USP Class VI, ADCF, gamma stable high-density polyethylene (HDPE)
Maximum speed	210 rpm
Impeller biocontainer location	Center, off-center

Parameter	LevMixer drive unit
Power	Single phase 100 or 230 V AC, 50/60 Hz
Input wattage	< 350 W
Drive unit footprint	40 × 112 cm (16 × 44 in.)
Drive unit height	92 cm top of control box (36 in.)
Drive unit weight	32.2 kg (70.99 lbs)
Hardware	304 L stainless steel frame (≤ 35 µin. Ra)
IP rating	Control box: IP65 Drive unit enclosure: IP23
Remote control	Impeller speed out 4 to 20 mA Discrete input/output (I/O) for start/stop/alarm

Fig 2. LevMixer impeller with drive unit head underneath.

Principle of operation

The mixing technology of the LevMixer system is based on non-contact magnetic coupling between conventional permanent magnets in the impeller and superconducting material in the drive (Figure 3). Superconducting material has the ability to 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 peculiar nature of magnet superconductor interaction ties the two bodies together resulting in a very stable magnetic coupling with finite equilibrium separation. This system is housed in a universal drive unit (Figure 4).

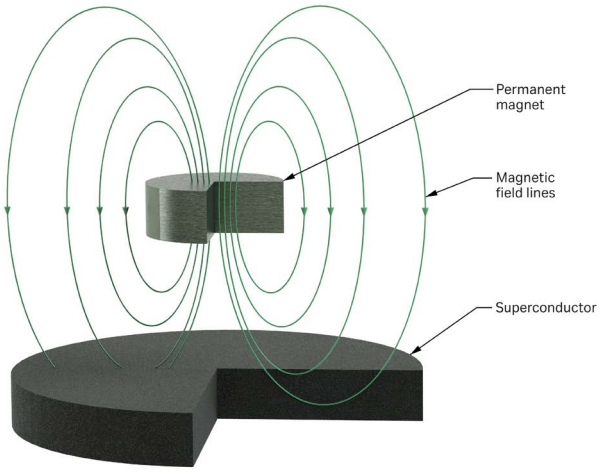

Fig 3. Principle of operation for LevMixer impeller.

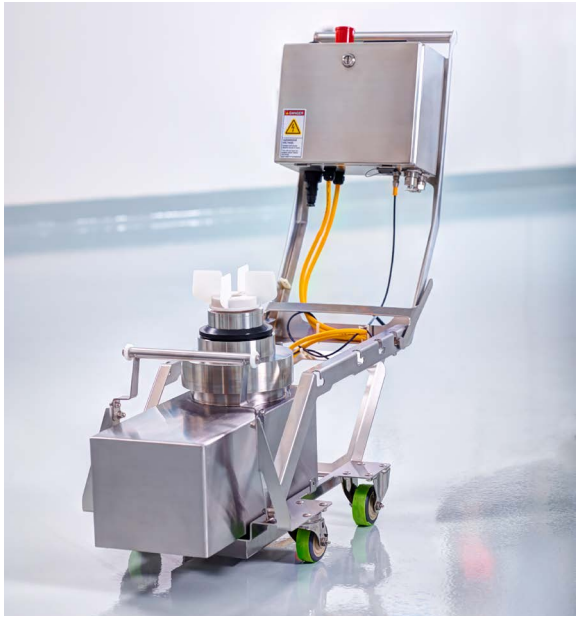

Fig 4. LevMixer drive unit with test impeller.

Ordering information

LevMixer drive unit and power cords

Product	Product code
LevMixer universal drive unit	LT-DBTL300
Power cord USA (already included with drive unit)	LT-SVSP365
Power cord Europe (already included with drive unit)	LT-SVSP366
Power cord Australia (required accessory this country)	LT-SVSP367
Power cord Switzerland (required accessory this country)	LT-SVSP368
Power cord United Kingdom (required accessory this country)	LT-SVSP369
Power cord China (required accessory this country)	LT-SVSP480

LevMixer standard SUS, round

Product	Product code
30 L round, 2 in. powder port, Allegro film	6403-1157B
50 L round, 4 in. powder port, Allegro film	6403-1156X
100 L round, 4 in. powder port, Allegro film	6403-1121K
200 L round, 4 in. powder port, Allegro film	7403-0998Q
350 L round, 4 in. powder port, Allegro film	6403-1121J
500 L round, 4 in. powder port, Allegro film	7403-0998S
1000 L round, 4 in. powder port, Allegro film	6403-1247R

LevMixer standard SUS, cubical

Product	Product code
50 L cubical, 4 in. powder port, Allegro film	6403-1221T
100 L cubical, 4 in. powder port, Allegro film	6403-1158K
200 L cubical, 4 in. powder port, Allegro film	6403-1156V
400 L cubical, 4 in. powder port, Allegro film	7403-1086Z
650 L cubical, 4 in. powder port, Allegro film	7403-1105E
1000 L cubical, 4 in. powder port, Allegro film	6403-1157G

LevMixer standard SUS, general use

Product	Product code
50 L cubical general use design, 4 in. powder port, Allegro film	7403-1624U
100 L cubical general use design, 4 in. powder port, Allegro film	7403-1626T
200 L cubical general use design, 4 in. powder port, Allegro film	7403-1626U
400 L cubical general use design, 4 in. powder port, Allegro film	7403-1626Y
650 L cubical general use design, 4 in. powder port, Allegro film	7403-1626Z
1000 L cubical general use design, 4 in. powder port, Allegro film	7403-1627A

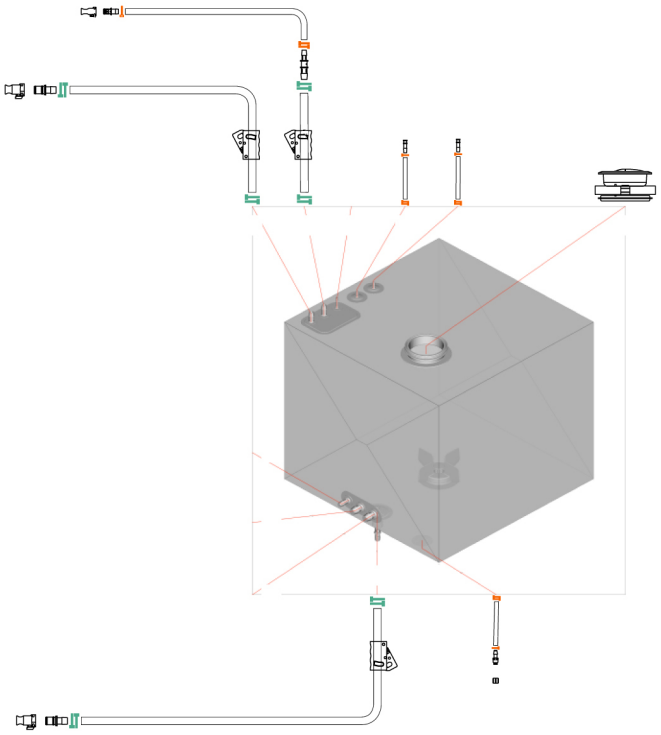

Fig 5. Example standard cubical design (also applicable to standard round) for standard mixing applications with 2 inlets, powder port, bottom drain and sample valve.

Representative drawing only for more detailed drawings please contact Cytiva.

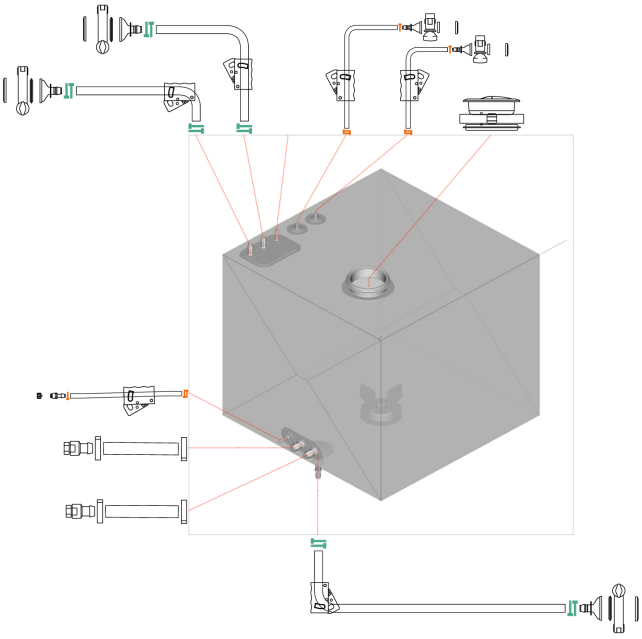

Fig 6. Example standard general use design, for open processing with vendor agnostic/universal sanitary flange connections. General use designs have 2 main inlets, 2 side inlets, powder port, sampling port, 2 sensing ports and a bottom drain. The design is made to be as universal as possible and it is optimized for sensing, pH adjustment and media prep applications among others.

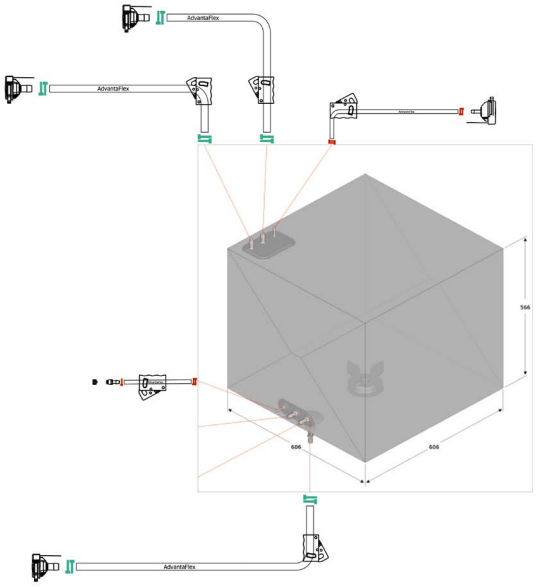

Fig 7. Example standard filtered product and filtered product sanitary outlet design. The filtered product line is designed for closed processing (e.g. no open powder port). The biocontainers have 2 main inlets and a smaller side inlet, all with Kleenpak™ Presto sterile connectors for closed processing. It also contains a sampling port and a bottom outlet. The filtered product design has a Kleenpak Presto sterile connector on the outlet, whereas the filtered product sanitary outlet design has a sanitary flange outlet for direct connection to sterile filters.

LevMixer standard SUS, filtered product

Product	Product code
50 L cubical filtered product, sanitary outlet design, Allegro film	7403-1630T
100 L cubical filtered product, sanitary outlet design, Allegro film	7403-1630U
200 L cubical filtered product, sanitary outlet design, Allegro film	7403-1630Y
400 L cubical filtered product, sanitary outlet design, Allegro film	7403-1630W
650 L cubical filtered product, sanitary outlet design, Allegro film	7403-1631A
1000 L cubical filtered product, sanitary outlet design, Allegro film	7403-1631B
50 L cubical filtered product design, Allegro film	7403-1350S
100 L cubical filtered product design, Allegro film	7403-1351N
200 L cubical filtered product design, Allegro film	7403-1352K
400 L cubical filtered product design, Allegro film	7403-1352N
650 L cubical filtered product design, Allegro film	7403-1352U
1000 L cubical filtered product design, Allegro film	7403-1356W

In addition to the above standard Allegro mixer systems, we can also offer single-use customized systems with the Advanced Central Management System (ACMS). For further information and drawing requests, please contact us.

Fig 8. Plastic container on dolly (LEV500PR tank and LM-DBMC037 dolly).

Mixing tanks

The tanks or containers for the SU biocontainers can be made out of plastic, which offer a price advantage, or SS. The SS variants are available with load cells and/or thermal control jacket (available with ASME certification). Both plastic and SS tanks can be used with the Magnetic Mixer or the LevMixer technologies and their associated biocontainers.

Plastic tanks

Product: medium density polyethylene (MDPE) round tank	Product code
30 L round MDPE mixing container (minimum agitation volume 4 L)	LEV30PR
50 L round MDPE mixing container	LEV50PR
100 L round MDPE mixing container	LEV100PR
200 L round MDPE mixing container	LEV200PR
350 L round MDPE mixing container	LEV350PR
500 L round MDPE mixing container	LEV500PR

LevMixer and Magnetic Mixer dolly for plastic tanks

Product	Product code
Dolly full handle, compatible with probe support LT-SVSP471	LM-DBMC037
Dolly partial handle, compatible with probe support LT-SVSP471	LM-DBMC038

Stainless steel (SS) tanks

Product: SS (AISI 304) cubical container	Product code
50 L, SS cubical container	LM50NCN-B4N
100 L, SS cubical container	LM100NCN-B4N
200 L, SS cubical container	LM200NCN-B4N
400 L, SS cubical container	LM400NCN-B4N
650 L, SS cubical container	LM650NCN-B4N
1000 L, SS cubical container	LM1000NCN-B4N

Product: SS (AISI 304) cubical container with load cells	Product code
50 L, SS cubical container, with load cells	LM50NCMA-B4N
100 L, SS cubical container, with load cells	LM100NCMA-B4N
200 L, SS cubical container, with load cells	LM200NCMA-B4N
400 L, SS cubical container, with load cells	LM400NCMA-B4N
650 L, SS cubical container, with load cells	LM650NCMA-B4N
1000 L, SS cubical container, with load cells	LM1000NCMA-B4N

Product: SS (AISI 304) cubical container, jacketed (non ASME)	Product code
50 L, SS cubical container, jacketed	LM50JCN-B4N
100 L, SS cubical container, jacketed	LM100JCN-B4N
200 L, SS cubical container, jacketed	LM200JCN-B4N
400 L, SS cubical container, jacketed	LM400JCN-B4N
650 L, SS cubical container, jacketed	LM650JCN-B4N
1000 L, SS cubical container, jacketed	LM1000JCN-B4N

Product: SS (AISI 304) cubical container, jacketed (non-ASME) with load cells	Product code
50 L, SS cubical container, jacketed, with load cells	LM50JCMA-B4N
100 L, SS cubical container, jacketed, with load cells	LM100JCMA-B4N
200 L, SS cubical container jacketed, with load cells	LM200JCMA-B4N
400 L, SS cubical container, jacketed, with load cells	LM400JCMA-B4N
650 L, SS cubical container, jacketed, with load cells	LM650JCMA-B4N
1000 L, SS cubical container, jacketed, with load cells	LM1000JCMA-B4N

Product: SS (AISI 304) cubical container, jacketed (ASME certified)	Product code
50 L, SS cubical container, jacketed (ASME)	LM50JCN-B4A
100 L, SS cubical container, jacketed (ASME)	LM100JCN-B4A
200 L, SS cubical container, jacketed (ASME)	LM200JCN-B4A
400 L, SS cubical container, jacketed (ASME)	LM400JCN-B4A
650 L, SS cubical container, jacketed (ASME)	LM650JCN-B4A
1000 L, SS cubical container, jacketed (ASME)	LM1000JCN-B4A

Product: SS (AISI 304) cubical container, jacketed (ASME certified) with load cells	Product code
50 L, SS cubical container, jacketed (ASME), with load cells	LM50JCMA-B4A
100 L, SS cubical container, jacketed (ASME), with load cells	LM100JCMA-B4A
200 L, SS cubical container, jacketed (ASME), with load cells	LM200JCMA-B4A
400 L, SS cubical container, jacketed (ASME), with load cells	LM400JCMA-B4A
650 L, SS cubical container,jacketed (ASME), with load cells	LM650JCMA-B4A
1000 L, SS cubical container, jacketed (ASME), with load cells	LM1000JCMA-B4A

Product: power cord for mixers with load cells	Product code
US power cord (required accessory for load cells)	LT-SVSP365
Europe power cord (required accessory for load cells)	LT-SVSP366
Australian power cord (required accessory for load cells)	LT-SVSP367
Switzerland power cord (required accessory for load cells)	LT-SVSP368
United Kingdom power cord (required accessory for load cells)	LT-SVSP369
Chinese power cord (required accessory for load cells)	LT-SVSP480

Technical specifications

SS tanks

General specifications

General category	Parameter	Specification
Facility	Materials of construction	304 SS Wheels: polyamide
	Surface finish Ra	Brush polished: ≤ 0.89 µm (35 µin)
Load cells	Type	50 to 400 L: Minebea PR6211 650 to 1000 L: Minebea PR6212
	Quantity	3
	Range	Nominal volume of size container
	Accuracy	0.3% of maximum nominal volume
	Indicator type	Midrics 2
	Indicator output	4 to 20 mA
	Indicator connector	Female PG7 Binder (3 pole) 
	Ingress protection rating	Junction box: IP65 Load cell indicator: IP65
	Electrical supply	Single phase 115 V to 230 V AC, 50/60 Hz
	Cable (6 m/20 ft)	US: NEMA 5-15  EU: CEE7/7 
	Electrical safety	CE
	Printer	Cleanroom compatible printer available on request
Jacket	Type	Dimple jacket
	Insulation	Rockwool or Superwool Plus 2 in. thick
	Temperature range	-5/90°C (23/194°F)
	Jacket connections	1½ in. sanitary connection
	Jacket pressure rating	Maximum 6.2 bar/90 psi
	Regulatory compliance	Pressure Equipment Directive (PED) 2014/68/EU
	Regulatory compliance ASME variant	ASME BPVC section VIII div.1 code certification stamp: U

Tank operating volumes and dimensions

	Operating volumes	LevMixer drive
50 L mixer tank	Maximum	50 L
	Agitation (minimum)	7 L
	Mixing (minimum)	16 L
	Sensing (minimum)	13 L
	Dimensions (weight)	**Width × length × height**
	LM50NCN (58 kg/128 lbs.)	74.5 × 78.9 × 93.9 cm (29.3 × 31.1 × 37.0 in.)
	LM50JCN (99 kg/218 lbs.)	72.3 × 78.4 × 94.1 cm (28.5 × 30.9 × 37.0 in.)
	LM50NCMA (90 kg/176 lbs.)	74.6 × 92.2 × 139.3 cm (29.4 × 36.3 × 54.8 in.)
	LM50JCMA (127 kg/280 lbs.)	75.0 × 92.2 × 139.3 cm (29.5 × 36.3 × 54.8 in.)
100 L mixer tank	Maximum	100 L
	Agitation (minimum)	8 L
	Mixing (minimum)	22 L
	Sensing (minimum)	17 L
	Dimensions (weight)	**Width × length × height**
	LM100NCN (83 kg/183 lbs.)	84.9 × 86.0 × 105.4 cm (33.4 × 33.9 × 41.5 in.)
	LM100JCN (130 kg/287 lbs.)	80.3 × 84.4 × 105.6 cm (31.6 × 33.2 × 41.6 in.)
	LM100NCMA (150 kg/331 lbs.)	85.5 × 126.6 × 158.0 cm (33.7 × 49.8 × 62.2 in.)
	LM100JCMA (204 kg/450 lbs.)	85.5 × 126.6 × 158.0 cm (33.7 × 49.8 × 62.2 in.)
200 L mixer tank	Maximum	200 L
	Agitation (minimum)	12 L
	Mixing (minimum)	34 L
	Sensing (minimum)	25 L
	Dimensions (weight)	**Width × length × height**
	LM200NCN (107 kg/236 lbs.)	80.7 × 86.0 × 115.8 cm (31.8 × 33.9 × 45.6 in.)
	LM200JCN (179 kg/395 lbs.)	85.0 × 87.9 × 116.0 cm (33.5 . × 34.6 × 45.7 in.)
	LM200NCMA (176 kg/388 lbs.)	85.5 × 126.6 × 158.0 cm (33.7 × 49.8 × 62.2 in.)
	LM200JCMA (255 kg/562 lbs.)	85.8 × 126.6 × 158.0 cm (33.8 × 49.8 × 62.2 in.)
400 L mixer tank	Maximum	400 L
	Agitation (minimum)	19 L
	Mixing (minimum)	56 L
	Sensing (minimum)	40 L
	Dimensions (weight)	**Width × length × height**
	LM400NCN (156 kg/344 lbs.)	98.3 × 109.0 × 130.8 cm (38.7 × 42.9 × 51.5 in.)
	LM400JCN (262 kg/578 lbs.)	101.6 × 105.9 × 131.0 cm (40.0 × 41.7 × 51.6 in.)
	LM400NCMA (215 kg/474 lbs.)	95.0 × 126.6 × 158.0 cm (37.4 × 49.8 × 62.2 in.)
	LM400JCMA (336 kg/741 lbs.)	101.6 × 126.6 × 158.0 cm (40.0 × 49.8 × 62.2 in.)
650 L mixer tank	Maximum	650 L
	Agitation (minimum)	25 L
	Mixing (minimum)	76 L
	Sensing (minimum)	55 L
	Dimensions (weight)	**Width × length × height**
	LM50NCN (198 kg/437 lbs.)	111.0 × 115.4 × 144.7 cm (43.7 × 45.4 × 57.0 in.)
	LM50JCN (368 kg/811 lbs.)	115.2 × 122.1 × 144.4 cm (45.4 × 48.1 × 56.9 in.)
	LM650NCMA (299 kg/659 lbs.)	113.1 × 147.8 × 153.7 cm (44.5 × 58.2 × 60.5 in.)
	LM650JCMA (468 kg/1032 lbs.)	115.2 × 147.8 × 153.7 cm (45.4 × 58.2 × 60.5 in.)

	Operating volumes	Magnetic Mixer drive
1000 L mixer tank	Maximum	1000 L
	Agitation (minimum)	33 L
	Mixing (minimum)	100 L
	Sensing (minimum)	73 L
	Dimensions (weight)	**Width × length × height**
	LM1000NCN (257 kg/567 lbs.)	124.7 × 129.6 × 160.2 cm (49.1 × 51.0 × 63.1 in.)
	LM1000JCN (484 kg/1067 lbs.)	128.9 × 129.9 × 159.9 cm (50.8 × 51.1 × 63.0 in.)
	LM1000NCMA (357 kg/787 lbs.)	121.7 × 152.8 × 160.3 cm (47.9 × 60.1 × 63.1 in.)
	LM1000JCMA (583 kg/1285 lbs.)	129.1 × 153.3 × 159.9 cm (50.8 × 60.4 × 63.0 in.)

Fig 9. Example tanks: 1000, 400, and 200 L (shown with load cells).

Minimum working volumes for each single-use mixer

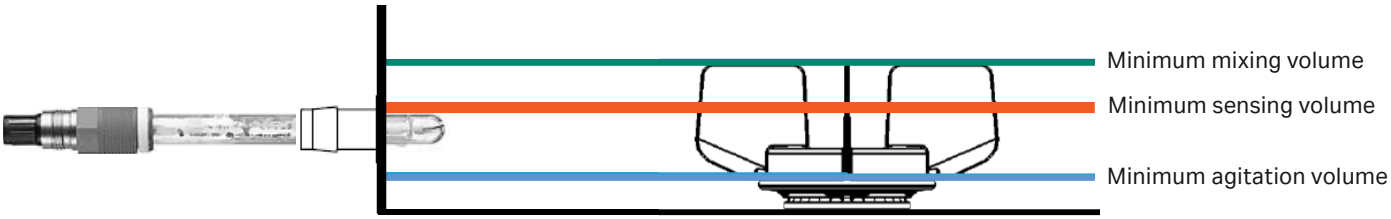

Fig 10. Minimum volume criteria for single-use mixers.

Minimum mixing volume – the volume required to completely immerse the impeller blades at rest where liquid-liquid mixing is effective; mixing may not be adequate for some applications (e.g., challenging solid-liquid mixing).

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

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

Automation

For data transfer and/or control via an external control system (decentralized control system [DCS] or supervisory control and data acquisition [SCADA] system), we can offer the control box along with the Magnetic Mixer drive unit for automated applications (Product code: MMG403). The control box allows data transfer and external control via DCS or SCADA system. It is available in 2 variants, the basic and the advanced version.

Product	Product code
LevMixer drive unit Gen IV – CE/UL	LMG403

Basic control box:

Product	Product code
Basic controller – temperature and weight; PLC – CE version (230 V)	CBG401B
Basic controller – temperature and weight; PLC – UL version (120 V)	CBG402B

The basic control box provides the following functionality:

- RJ45 ethernet socket via ethernet cable for S7/S7 PLC interface (for Allegro MVP system interface)
- RJ45 ethernet socket data access via OPC/UA (for DCS/SCADA interface)
- Weight 4 to 20 mA (when connected to an appropriate tank including load cells)
- Temperature cable and PT100

Fig 11. Left: basic control box for drive unit, temperature and load cell integration. **Right:** for automation integration designed LevMixer drive unit LMG403.

Advanced control box

Product	Product code
Advanced control box – pH, conductivity, temperature, weight; PLC – CE (230 V)	CBG401A
Advanced control box – pH, conductivity, temperature, weigh; PLC – UL (120 V)	CBG402A

The advanced control box provides the following functionality:

- RJ45 ethernet socket via ethernet cable for S7/S7 PLC interface (for Allegro MVP system interface)
- RJ45 ethernet socket data access via OPC/UA (for DCS/SCADA interface)
- Weight 4 to 20 mA (when connected to an appropriate tank including load cells)
- Temperature cable and PT100
- Mettler-Toledo M300 transmitter for integration of on-line pH and conductivity via digital ISM sensors

Fig 12. Advanced control box for drive unit, temperature, pH, conductivity, and load cell integration.

Fig 13. LevMixer drive unit LMG403 with advanced control box CBG401A and 400 L SS tank.

Standalone automation

If you do not have an SCADA or DCS system but you still need data transfer for regulatory requirements (e.g. 21 CFR Part 11 compliance), we can help. The Allegro MVP system offers amongst many other features full local control and automation for mixing systems without the need for any external control system.

Fig 14. LevMixer (or Magnetic Mixer) system can be paired with the Allegro MVP system for full automation without the need for a local SCADA or DCS system.

The full mixing experience

Whenever there are mixing applications, there are often powder handling, temperature (need for a temperature control unit), inflation, liquid handling or sterile filtration requirements. Cytiva is able to deliver a mixing experience that meets these varied requirements.

Fig 15. Powder bag lift with bag attached.

Fig 16. Temperature control unit from Lauda, which can be offered in a one-stop-shop package for mixing – allowing trouble-free integration and time-savings.

Fig 17. Inflation box for the optional inflation of mixing biocontainers. This allows mixing down to the above-mentioned agitation volume.

For more information on our inflation box, temperature control units, transfer/storage/filtration sets and other questions, please contact us.

cytiva.com

For local office contact information, visit cytiva.com/contact

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