LevMixer™ 10 L single-use mixer

SINGLE-USE MIXING SYSTEM

A compact and scalable system well suited for mixing small volumes of shear-sensitive fluids.

The LevMixer™ 10 L single-use (SU) mixer is a flexible, benchtop system designed for efficient and reproducible small-scale mixing (Fig 1). With a mixing volume range from 100 mL to 10 L, the system is characterized for process scale-up using larger Cytiva mixing systems available within the LevMixer product family. Ready-to-use, gamma-irradiated biocontainers with optional, pre-installed, single-use pH sensors and inflation lines reduce setup time and process risk.

Our local software, mPath™ link is suitable for use in a GxP-regulated environment enabling support for 21 CFR Part 11 requirements. To enable full traceability, data integrity, and compliance with GxP standards, an available tool set integrates the system in your GxP-compliant facility. It automates processes, logs every action, and provides comprehensive documentation to support high-quality, compliant bioprocessing operations.

This system incorporates a levitating impeller that reduces risks of particle generation and minimizes the effects of shear that can damage sensitive fluids. It can be operated locally or remotely with integrated process monitoring and control capabilities for key process parameters.

The LevMixer 10 L single-use mixing system is engineered to take processes from discovery to drug delivery and is designed to be used in process development or GxP production environments.

Features and benefits

- 100:1 turndown ratio provides broad process volume flexibility
- Local or remote-control options align with different automation preferences and facility environments
- Designed to work in a GxP environment in either local or remote configuration
- Temperature control capabilities (optional)
- Pre-installed, single-use pH sensor (optional)
- In-process monitoring of speed, temperature, pH, and weight
- Broad impeller speed range for gentle or powerful mixing
- Sloped bottom of mixing tank increases product recovery
- Levitating impeller avoids particle generation and limits shear
- Stainless steel mixing tank is robust and easily cleanable
- Pre-configured and customizable consumables
- Compact hardware designed to easily fit on a benchtop



Fig 1. The LevMixer 10 L single-use mixing system is a compact mixer designed for low-volume applications.

Recommended applications

The LevMixer 10 L mixing system is well suited for small-volume applications within workflows to produce gene therapies, standard or high-concentration monoclonal antibodies, recombinant proteins, or nucleic acids. The mixer has the flexibility to be used for powder-liquid or liquid-liquid mixing from upstream to downstream in process development (PD) and cGMP environments.

Example process steps include:

- Buffer preparation
- Media preparation
- Reagent preparation for lipid nanoparticles
- Neutralization
- pH adjustment
- Product hold and intermediate process steps
- Tangential flow filtration (TFF) retentate vessel
- Viral inactivation
- Fill and finish
- Surge vessel

System overview

The LevMixer 10 L single-use mixing system has two main elements (Fig 2):

- Single-use system (consumables)
- Hardware system (main instrument)

The system can be controlled and monitored in two ways:

- Locally using the mPath™ link human-machine-interface (HMI) software[1]
- Remotely using a central control system via a Distributed Control System (DCS) or Programmable Logic Controller (PLC)/Supervisory Control and Data Acquisition (SCADA)

[1] Local control option requires the separate license of mPath link GxP-ready software either as a standalone license or along with a Cytiva provided PC.



Fig 2. LevMixer 10 L single-use mixing system with a biocontainer installed inside hardware during operation.

Single-use system (consumables)

The LevMixer 10 L single-use mixing system uses disposable mixing biocontainers primarily constructed from Allegro™ film (Fig 3). The biocontainers include integrated ports, tubing, connectors, and a levitating magnetic impeller (Fig 4). They are animal derived component free (ADCF) and comply with USP Class VI requirements.

The consumables are available in pre-configured or customizable options with different connector types, port types, and port locations. In addition, there are optional pre-installed, single-use pH sensors as well as optional inflation lines. Variants available are designed for either liquid-liquid or powder-liquid mixing applications.

The bottom of the single-use mixing system includes a base optimized for low volume performance by minimizing splashing and maximizing fluid recovery.



Fig 3. Allegro film biocontainer being installed into the hardware system.



Fig 4. Top-down view of the single-use impeller shown inside a single-use mixing base, which has been optimized for low-volume mixing and sensing.

Biocontainer configuration table

Pre-configured variants of the biocontainer are available as standard solutions. See ordering table for additional details. For all other configurations, reach out to a Cytiva representative to learn more about customization capabilities.

The standard MPC connector design is the most basic, with one bottom inlet and one outlet line, both with MPC connectors. The MPC design also contains a sampling line. There is no powder port, no single-use pH sensor, and no inflation line on this design.

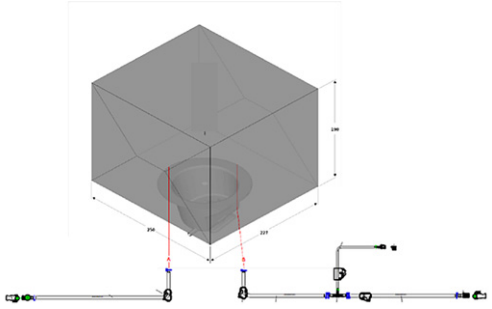
General-use biocontainer designs are well suited for open processing, including vendor agnostic Tri-Clamp sanitary flange connections. General-use designs have one bottom inlet, two top inlets, a powder port, an outlet port with sampling, and a thermowell for temperature sensing. Optional features include a pre-installed, single-use pH sensor and inflation line. The design is made to be as universal as possible, and it is well suited for pH adjustment, buffer prep, media prep, and other applications.

The aseptic processing designs are intended for closed processing (e.g., no open powder port). These biocontainers have one bottom inlet, two top inlets, and an outlet line, all with intrinsic sterile connectors for closed processing. The design also includes a thermowell for temperature sensing and a sampling line. Optional features include a pre-installed, single-use pH sensor and inflation line.

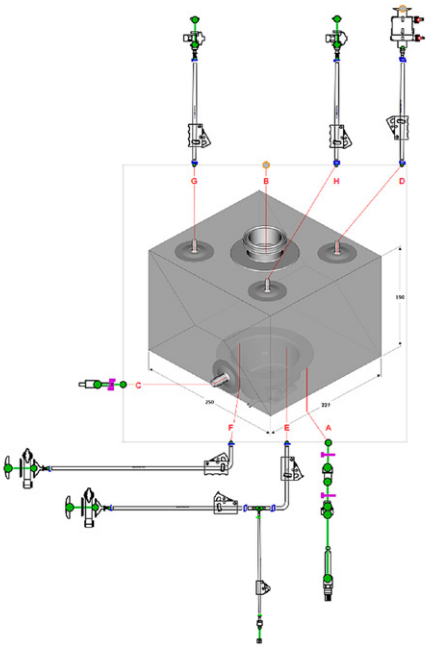
Table 1. Biocontainer attributes

Biocontainer configuration	Single-use pH probe	Connector Type	Powder port	Thermowell	Sample port	Fluid inlets	Fluid outlet	Inflation line	Gamma-irradiated
Standard	No	¼" MPC	No	Front face	⅛" female, needle-free, swabable luer on outlet line	One total Bottom: 1× ¼"	One drain Bottom: 1× ¼"	No	Yes
General use	Optional	1 ½" Tri-Clamp (inlet and outlet) ¾" Tri-Clamp (fluid addition lines)	Yes	Front face	⅛" female, needle-free, swabable luer on outlet line	Three total Top: 2× ¼" Bottom: 1× ¼"	One drain Bottom: 1× ¼"	Optional	Yes
Aseptic processing	Optional	Cytiva Kleenpak™ Presto or AseptiQuik™	No	Front face	⅛" female, needle-free, swabable luer on outlet line	Three total Top: 2× ¼" Bottom: 1× ¼"	One drain Bottom: 1× ¼"	Optional	Yes

Standard with MPC connectors



General use (shown with single-use pH probe and inflation line)



Aseptic processing (shown with single-use pH probe and inflation line)

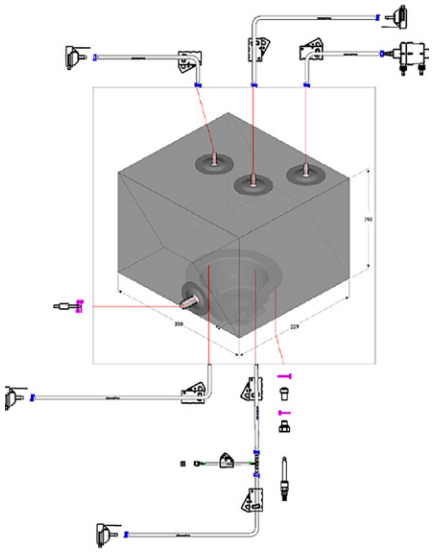


Table 2. Single-use assembly features

Attribute	Value	Description
Mixing (minimum)	100 mL	The volume required to completely immerse the impeller blades at rest where liquid-liquid mixing is effective
Mixing (maximum)	10 000 mL	Maximum recommended mixing volume
Bottom inlet	¼" inlet tubing	The agitation assembly is provided with a ¼" inlet
Bottom outlet	¼" outlet tubing	The agitation assembly is provided with a ¼" outlet
Angle of slope	10°	The angle of the base that maximizes drainability
Sampling port	⅛" female, needle-free luer	On our pre-configured biocontainer assemblies, the outlet line includes a ⅛" needle-free luer sampling port

Hardware system

The hardware system consists of a compact, 10 L capacity, stainless steel mixing system (Fig 5) designed to fit easily on a benchtop. It includes an integrated drive unit used to rotate a single-use, levitating impeller. Additionally, the system includes a built-in load cell for accurate weight sensing and an optional on-board pH transmitter for pH and temperature sensing. It optionally includes a thermal jacket for heating and cooling from 4°C to 40°C (Fig 6). For temperature control, the system must be paired with a thermal control unit (TCU), sold separately.

The front door of the system includes a viewing window for process visibility. The door swings open, allowing for easy installation of the biocontainer.

Additionally, the system includes a built-in probe support mechanism for applications where a single-use pH probe is needed.

An ethernet communication port provides seamless connectivity to both local and remote-control systems for efficient and reliable data exchange for enhanced operational control and monitoring.

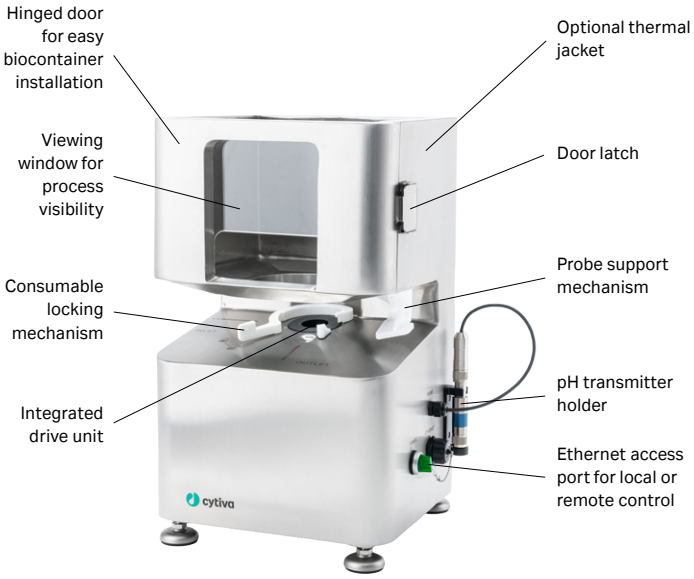


Fig 5. Main elements of the LevMixer 10 L hardware system.



Fig 6. A jacketed mixer includes thermal surface areas on three sides and the bottom. Temperature control is available from 2.5 L and above based on the location of the PT-100 temperature sensor thermowell in accompanying biocontainers.

Controlling the system

The system can be controlled either locally or remotely over Ethernet-based protocols via the communication port on the hardware system.

For local control, the system must be paired with mPath link software, sold separately as either a standalone license or along with a Cytiva provided PC. The mPath link software allows users to monitor and control the system via data recording, recipe management, and alarm management. The system is GxP compliant, supporting domain integration with user access profiles, enabling support for 21 CFR Part 11 compliance.

When selecting the hardware in its local software configuration, one hardware system is linked to one local software HMI.

If you need to link multiple systems to one networked software, use the mPath link V3 software. This software allows you to connect multiple mixer hardware systems. For more information visit the mPath link software page: cytivalifesciences.com/mPathlink

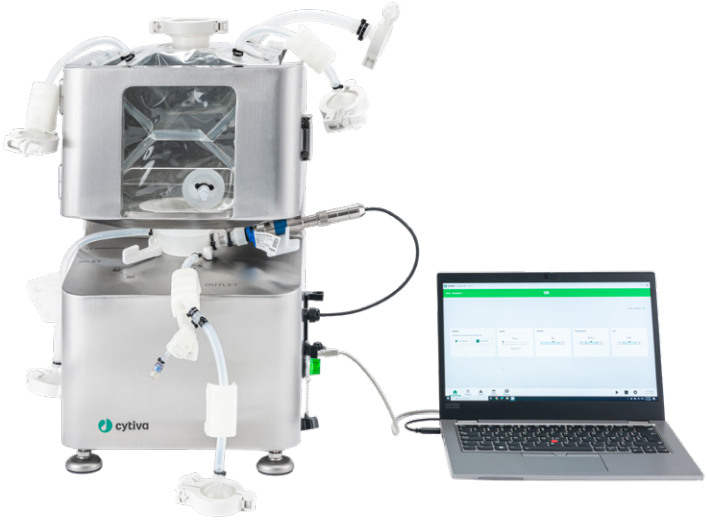


Fig 7. LevMixer 10 L single-use mixing system controlled locally with a computer.

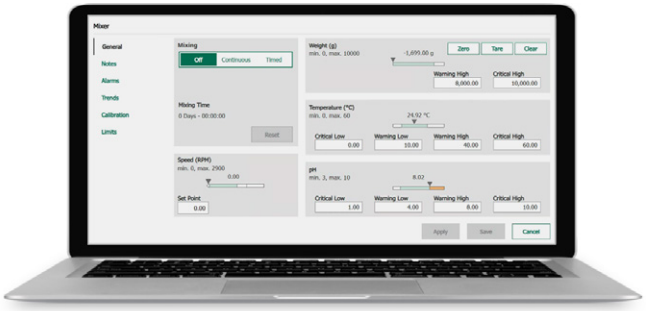


Fig 8. Software provided with the system can be used to control speed and monitor pH, temperature, and weight locally from an intuitive interface.

The system comes with the following as standard:

- RJ45 Ethernet socket with multiprotocol I/O (Profinet, EtherNet/IP, Modbus TCP).
- Integration and communication guide outlining remote programming via the device abstraction layer (DAL).

External TCU (optional)

Cytiva collaborates with Lauda to provide temperature control systems, which can be purchased separately.

- Recommended TCU: Variocool VC1200 NRTL (air- and water-cooled options)
- Temperature cable and PT100 temperature sensors
- Testing of the mixer system with Lauda TCU systems has demonstrated:
  - Temperature can be controlled between 4° and 40°C at 10 L.
  - Product temperature reaches 4°C from room temperature in under 2 h.
  - Product temperature reaches 40°C from room temperature in under 2 h.
  - Room temperature to 4°C or 40°C in under 82 min using multiple conditions and fill volumes ranging from 2.5 L to 10 L.



Fig 9. A temperature control unit from Lauda, which can be offered in a one-stop-shop package for mixing, allows trouble-free integration and time-savings.

Technical specifications: single-use system

Single-use impeller

Type	Radial flow, levitating
Number of blades	Five (5)
Materials of construction	Single magnet encased in polypropylene (PP) biocompatible (FDA, USP-VI, BSE/TSE, and animal-free)
Speed range	10 to 2900 rpm
Impeller biocontainer location	Bottom center
Number of impellers	One (1)
Diameter	42 mm
Blade height	12 mm

Single-use biocontainer

Shape	Cubical
Maximum pressure	20 mbar peak 15 mbar continuous (if inflated)
Operating temperature range	4°C to 40°C
Maximum mixing volume	10 L
Minimum mixing volume (without pH sensor)	100 mL
Minimum mixing volume (with optional pH sensor)	200 mL
Residual volume without manipulation[3]	< 50 mL
Residual volume with manipulation[3]	< 15 mL
Slope of consumable base toward drain by design (bottom cup only)	10°
Sterilization method	Gamma irradiation
Gamma irradiation level	25 – 50 kGy
Durability	24 h of continuous use
Shelf life post gamma irradiation (without single-use pH sensor)	24 mo
Shelf life post gamma irradiation (with pH sensor)	24 mo
Maximum viscosity of process fluid	25 cP
Film type	Allegro film
Fluid contact layer material of film	Ultra-low-density polyethylene (ULDPE)
Gas barrier layer material of film	Ethylene vinyl alcohol (EVOH)
Ports and fitting materials	High-density polyethylene (HDPE)
Standard tubing material	Platinum-cured silicone

[3] Manipulation implies any handling of the single-use system by an operator with the intent of draining as much of the fluid as possible.

Single-use pH sensor (optional)

Type	Disposable (pre-installed)
Brand	Hamilton™ OneFerm pH VP 70 NTC[4]
Range	pH 3 to 10
Probe length	70 mm
Probe diameter	12 mm
Electrical connector	VP6
Sensitivity	Before gamma irradiation: 57 to 60 mV/pH at 25°C (97% – 101%) Shift after gamma irradiation: ± 1.5 mV/pH
Accuracy	After gamma irradiation and dry storage: ± 0.15 pH with provided calibration values ± 0.1 pH after product calibration at the measurement temperature and within 2 pH units from the product calibration point
Calibration data	Provided on sensor label
Drift	< 0.1 pH per week after wet in time, in buffer pH 7
Integrated temperature sensor	NTC 22 kOhm

Inflation line (optional)

Type	Disposable (pre-installed)
Brand	Cytiva Kleenpak KA1 capsule with Emflon™ II membrane

[4] Gamma irradiation of Hamilton single-use pH sensor results in outflow of analyte into the biocontainer (creating visible particulates).

Technical specifications: optional local control system

General information: local control system

Primary material of PC casing	304 stainless steel
Input power voltage	Single phase 80 V to 265 V AC, 50/60 Hz
Input wattage	< 85 W
Dimensioning for external UPS	100W Single Phase 90VAC–230VAC 50/60 Hz
Maximum allowed switch time for UPS	5 ms at full power load.
Included plug types	IEC C8 to type B mains cable, USA and JP IEC C8 to type C mains cable, EU IEC C8 to type G mains cable, UK
System dimensions (width × height × depth)	175 × 560 × 350 mm
System weight	~ 1.2 kg PC only
Ingress protection (IP) rating	IP 20
Electrical safety	CE, UL
EMI (PC)	ICES 003, EN55032/KN32, EN55035/KN35 ETSI EN 300328 ETSI EN 301893
EMI (power supply)	EN62368-1:2014 EN55022:2015 conducted EN55022:2015 emission EN61000-3-2:2014 EN61000-3-3:2013 EN55035:2017
RoHS	2015/863
Local control	mPath link mixer HMI software application

Hardware specifications: local control system

Processor (CPU)	1 × INTEL i3-9100E 3.60 GHz
Memory	16 GB RAM
Storage media	500 GB or higher
Minimal peripherals	
Display	1 × HMI port
USB	2 × USB ports
LAN	1 × RJ45 port

Software: local control system

Operating system	Minimum Windows™ 10 IoT Ent 2019 LTSC
SCADA system	• Inductive automation with following modules: – Ignition perspective license – OPC UA server module – Ignition tag historian
Data storage (database)	Microsoft SQL Server Express 2019 or higher

Environmental: local control system

Operating altitude	≤ 2000 m
Storage temperature	-20°C to 60°C
Operating temperatures (PC)	0°C to 40°C
Relative humidity	20% to 80% (without condensation)
Wet environment	IP 20

Technical specifications: mixer hardware system

Mixing tank

Primary material of construction	304 stainless steel
Surface finish	Brush polished: Ra ≤ 89 µm
Input power voltage	Single phase 100 V to 240 V AC, 50/60 Hz
Input wattage	< 200 W (15 W typical)
System dimensions (length × width × height)	LM10NCTE-B4N: 350 × 320 × 570 mm (13.8 × 12.6 × 22.4 in.) LM10JCTE-B4N: 350 × 340 × 570 mm (13.8 × 13.4 × 22.4 in.) LM10JCTE-B4A: 350 × 340 × 570 mm (13.8 × 13.4 × 22.4 in.)
System weight	LM10NCTE-B4N: 28 kg (62 lbs) LM10JCTE-B4N: 32 kg (71 lbs) LM10JCTE-B4A: 32 kg (71 lbs)
Slope toward drain	10°
Welds	According to International Organization for Standardization (ISO) 15607 and ISO 5817 level D
Weld finish	Ground smooth and polished
Ingress Protection (IP) rating	IP 45
Electrical safety	CE, UL, KC
Remote control	Multiprotocol Ethernet I/O (Profinet, EtherNet/IP, Modbus TCP)
Local control	mPath link HMI software application
Included plug types	IEC C13 Mains Cable, 2 m, USA/JP IEC C13 Mains Cable, 2 m, EU IEC C13 Mains Cable, 2 m, UK

Thermal jacket

Jacket type	Dimpled and insulated
Jacket location	Right, left, back, and bottom walls of mixing tank
Approximate heat transfer area	0.165 m^2
Approximate jacket fluid volume	0.95 L
Jacket pressure rating	Max 6.2 bar
Jacket design temperature range	-5°C to 65°C
Jacket material	316 stainless steel
Insulation material	ROCKWOOL
Heat transfer fluid connections	½" sanitary connection
Regulatory compliance	American Society of Mechanical Engineers (ASME) Certification Stamp: UM (optional)
Volume range where heating and cooling is effective	2.5 – 10 L

Weighing system

Brand	Metter Toledo
Type	Single point load cell
Load cell capacity rating	100 kg
Accuracy	Full scale: ± 0.1% (± 12 g accuracy at 12 000 g load)* Better than ± 1% accuracy for any weight less than full scale (tested at 100 g and 1200 g)
Resolution	1 g

* Loadcell accuracy without a TCU connected.
With a TCU connected the full-scale accuracy is: ± 0.3% when the official hose kit with hose support is used. Slight changes in weight overtime are to be expected when a TCU is connected. Always tare right before adding or draining product.

Environmental operating conditions

Indoor or outdoor use	Indoor only
Altitude	≤ 2000 m
Environmental temperature	15°C to 25°C
Relative humidity	20% to 80% (without condensation)
Mains supply voltage fluctuations	± 3%
Wet environment	IP 45

Principle of operation

The technology of the LevMixer 10 L single-use mixing system is based on the principle of magnetic levitation. During operation, the single-use impeller stays suspended in the process fluid, contact free. There are no shafts or bearings required to operate the impeller, which prevents particle generation during operation (Fig 10).

The single-use agitation assembly includes an optional pH sensor located below the minimum mixing volume, which allows for continuous process monitoring. Additionally, a 10° sloped base within the consumable is angled toward the outlet providing drainability, which results in minimal product loss (Fig 11).

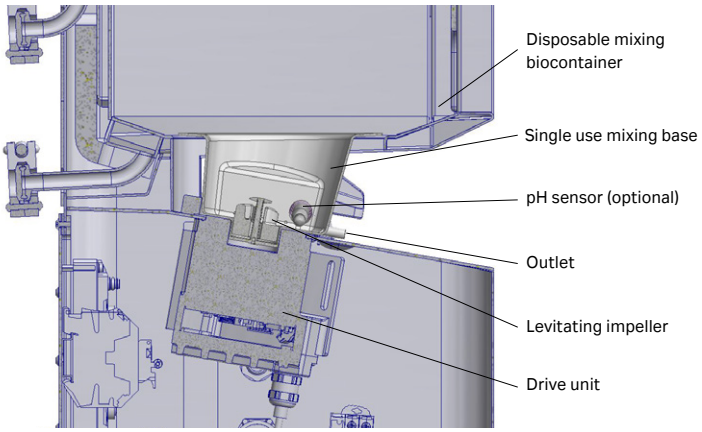


Fig 10. Cross-sectional view of LevMixer 10 L mixing system showing levitating impeller with drive unit underneath.



Fig 11. Sloped geometry in the single-use mixing base, which is part of the biocontainer, promotes maximum recovery and allows for low volume sensing.

Ordering information

Standard hardware system

Type	Description	Product code
Mixing hardware system	LevMixer 10 L single-use mixing system, jacketed with weight sensing (ASME certified)	LM10JCTE-B4A
	LevMixer 10 L single-use mixing system, jacketed with weight sensing	LM10JCTE-B4N
	LevMixer 10 L single-use mixing system, non-jacketed with weight sensing	LM10NCTE-B4N
Control system (optional)	3rd gen mPath link HMI – software with control system – LevMixer 10 L for 1 unit.	MPATHLINKV3-LEV
	3rd gen mPath link HMI – software only – LevMixer 10 L for 1 unit.	MPATHLINKV3-S-LEV

Spare parts and accessories

Type	Description	Product code
Power cords for mixing system hardware	Power cord for USA and Japan	LT-SVSP493
	Power cord for Europe	LT-SVSP494
	Power cord for UK	LT-SVSP495
	Power cord for Australia and China	LT-SVSP496
	Power cord for Switzerland	LT-SVSP497
Manual pump	Manual inflation system	LT-SVSP499

Temperature control unit (TCU) and associated accessories

Type	Description	Product code
TCU systems	Lauda Variocool VC1200 NRTL air-cooled temperature control unit	TCU-LA-V012A-UL
	Lauda Variocool VC1200 NRTL water-cooled temperature control unit	TCU-LA-V012W-UL
Hose kit	VC 1200 hose kit assembly	LT-SVSP498
Heat transfer fluid	KRYO 30 heat transfer fluid, 20 L unit	457-18091-00
Other TCU accessories	TCU pressure relief assembly	LT-SVSP500
	PT100 temperature sensor	457-18741-00
	PT100/LiBus module I/O interface	LRZ918
	Analog module I/O interface	LRZ912
	Contact module I/O interface	LRZ914

Standard single-use systems

Type	Description	Product code
Standard	10 L cubical biocontainer, MPC connectors, Allegro film	6403-1999Y
General-use	10 L cubical biocontainer, Tri-Clamp connectors, Allegro film	6403-1904U
	10 L cubical biocontainer, Tri-Clamp connectors, Allegro film, single-use pH probe	6403-1972K
	10 L cubical biocontainer, Tri-Clamp connectors, Allegro film, inflation lines	6403-2290Q
	10 L cubical biocontainer, Tri-Clamp connectors, Allegro film, single-use pH and inflation lines	6403-2290S
Aseptic processing	10 L cubical biocontainer, Presto connectors, Allegro film	6403-1904T
	10 L cubical biocontainer, Presto connectors, Allegro film, SU pH probe	6403-1972L
	10 L cubical biocontainer, Presto connectors, Allegro film, inflation lines	6403-2289A
	10 L cubical biocontainer, Presto connectors, Allegro film, SU pH and inflation lines	6403-2288Y
	10 L cubical biocontainer, AseptiQuik connectors, Allegro film	6403-2291Y
	10 L cubical biocontainer, AseptiQuik connectors, Allegro film, single-use pH probe	6403-2292L
	10 L cubical biocontainer, AseptiQuik connectors, Allegro film, inflation lines	6403-2292N
	10 L cubical biocontainer, AseptiQuik connectors, Allegro film, single-use pH and inflation lines	6403-2292M

The full mixing experience

Whenever you have mixing applications, you often require powder handling, temperature control, liquid handling, and/or sterile filtration. Cytiva can deliver a complete mixing experience with other products such as powder handling bags, filters, storage solutions, transfer sets, cell culture media, and more. Contact your Cytiva representative for more information other Cytiva products and end-to-end solutions.

Qualification services

Cytiva offers many services to accompany your equipment. Installation qualification and operational qualification (IQOQ), extended warranty,

Preventive maintenance, and other comprehensive service plans are available upon request. Please contact a Cytiva sales representative for more information.

Protect your equipment and optimize productivity

We recommend having the LevMixer 10 L single-use mixing system equipment serviced on an annual basis. Routine annual preventative maintenance (PM) of the instrument is essential for extended operation. PM must be performed by Cytiva-approved service engineers. The annual PM includes testing of all the LevMixer single-use mixing system internal components and sub-systems. Maintenance and/or repair work should not be undertaken by the user. Please contact your Cytiva representative for full details of our PM and calibration services.

Equipment service solutions

From installation to end of life, our equipment service solutions are designed to ensure your Cytiva equipment delivers maximum performance and value throughout its life cycle, so you can stay on schedule. Whether you have in-house support teams or plan to rely (fully or partially) on Cytiva, we offer flexible service options to meet your specific needs. Our engineers are certified, regularly recertified, and focused solely on servicing Cytiva equipment, providing hassle-free installation, repair and maintenance.

A comprehensive range of service plans, genuine parts engineered for reliability, standardized qualification services, and convenient remote troubleshooting support are available to protect your investment from day one. Preventive maintenance, tailored training, and cost-effective upgrade options are all designed to help minimize downtime throughout the equipment life cycle.

Find out more about our service solutions at cytiva.com/equipment-services or if you would prefer to contact a member of the equipment service solutions team visit cytiva.com/repair to locate your country specific phone number and e-mail address.

Description	Product code
LevMixer 10 L with load cell 24 month extended warranty (12 month extended)	29942993
LevMixer 10 L with load cell 36 month extended warranty (24 month extended)	29942994
LevMixer 10 L with load cell 48 month extended warranty (36 month extended)	29942995
LevMixer 10 L with load cell 24 month extended warranty (12 month extended)	29942996
LevMixer 10 L with load cell 36 month extended warranty (24 month extended)	29942997
LevMixer 10 L with load cell 48 month extended warranty (36 month extended)	29942998

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