SARTORIUS

Flexsafe®
for LevMixer®[1]

Product Information

Flexsafe® for LevMixer® offers low shear mixing performances for downstream intermediates, drug substances and drug product.

Description

Shear-sensitive proteins can degrade during mixing conditions. This can affect product quality and generate aggregates that in turn yield premature fouling of sterilizing filters.

By combining low shear mixing attributes and high torque, Flexsafe® for LevMixer® is ideal for the homogenization, viral inactivation and formulation of sensitive drug substances and drug products. The levitated impeller eliminates shear effects that can affect your product quality and avoid the generation of aggregates and particles that can reduce your filtration performance.

[1] LevMixer® is a trademark of Pall Corporation and this product uses Pall patented LevMixer® technology.

Features and Benefits

Using Flexsafe® for LevMixer® in your process steps provides you with:

- Low shear mixer
  Preserves your product quality and efficacy

- Unique in-line monitoring and control
  Consistent quality and process efficiency while meeting PAT and cGMP requirements

- Intuitive handling
  Quick start-up and simplified operations of your mixing bags in its Palletank®

- Large scale mixing offering
  Similar mixing technology for all your process and cGMP production scales.
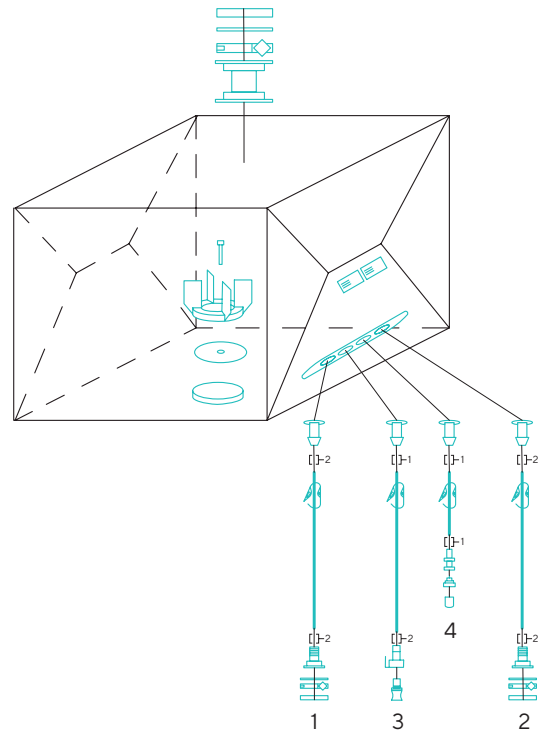
Technical Specifications

Product Specifications

The Flexsafe® for LevMixer® comprises three main components:

1. Flexsafe® bag for LevMixer®
2. Palletank® for Mixing
3. LevMixer® drive unit

1. Flexsafe® Bag for LevMixer®

The Flexsafe® bag for LevMixer® contains an in-center magnetic impeller assembly. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The eight-inch top port provides robustness avoiding contact of the impeller with the film during transport.

Standard Flexsafe® Bags for LevMixer® Specifications

Bag chamber	S80 multi-layer film Contact layer: LLDPE (Linear Low Density Polyethylene) Core layer: EVOH (Ethylene Vinyl Alcohol) External layer: LLDPE (Linear Low Density Polyethylene) 400 µm thickness
Impeller position	Bottom centered
Impeller size (50 L – 100 L)	4.95" (126 mm)
Impeller size (200 L – 1,000 L)	6.35" (161 mm)
Tubing material silicone	Silicone Tuflux® tubing

Standard Flexsafe® Bags for LevMixer® Specifications

Number of ports	8" top port, four front bottom ports
Outlet fittings	CPC quick coupler, Tri-clamp 1½" sanitary flange, needleless sampling port
Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L
Nominal filling volume 50 L 100 L 200 L 400 L 650 L 1,000 L	Minimum[2] – Maximum volume 30 L – 65 L 40 L – 120 L 60 L – 225 L 120 L – 420 L 160 L – 720 L 170 L – 1,050 L
Operating temperature range	5 – 40 °C
Sterilization	Gamma irradiation

[2] Minimum volume under aseptic conditions with closed bag

Line 1	Filling	½" ID Silicone Tuflux® 1.5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap and union
Line 2	Draining	½" ID Silicone Tuflux® 1.5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap and union
Line 3	Addition	⅜" ID Silicone Tuflux® 1.5 m (60") + MPC female + sealing cap
Line 4	Sampling	¼" ID Silicone Tuflux® 0.1 m (4") + Clave needleless sampling port

2. Palletank® for Mixing

The Palletank® for Mixing is a stainless steel cubical container designed to perfectly fit with the Flexsafe® bag for LevMixer® with its integrated impeller. It includes a railed port for coupling the mobile LevMixer® drive unit with the Palletank® and a clamp holder to facilitate powder transfer. The Palletank® for Mixing is also available as standard either with a heat exchange jacket and | or with integrated loadcells and weight indicator.

Palletank® for Mixing

Integrated Weighing

Description	Technical Specification
Scale Indicator	Minebea Combics 1
Material of construction	Stainless Steel 304
Keyboard	6 keys
Display	14 segments 20 mm weight readout
Interface	RS232
Connection to printer	Additional cable available as an option
IP protection rate	IP69K
Operating temperature range	-10 °C to 40 °C

Integrated load cells	Minebea Novego
Material of construction	304 and 4418 (sensor)
IP protection rate	IP68 + IP69
Overload	High overload protection
Vibration resistance	Resistance against oscillations (IEC 68-2-6 Fc); 20 g, 100 h, 10 to 150 Hz
Design	In accordance with European Hygienic Engineering and Design Group (EHEDG) guidelines
Lift-off	Lift-off protector and anti-wobbling mechanism

2.1 Palletank® for Mixing

Description	Volumes	Technical Specification
Volumes		50 L	100 L	200 L	400 L	650 L	1,000 L
Main construction materials	50 L to 1,000 L	Stainless Steel 304L Windows made of PC and EPDM sealing
Surface finish	50 L to 1,000 L	Acid cleaned, stainless steel bead blasted and passivated
Door	50 L to 400 L 650 L and 1,000 L	Front door and PC windows Front doors and PC windows
Bag tubing gate	50 L to 1,000 L	Front bottom port for bag lines	sensor access
Port	50 L to 1,000 L	Railed port for drive unit coupling
Mobility	50 L to 1,000 L	Mounted on stainless cart with four clean room wheels and push handles
Operating temperature	50 L to 1,000 L	0 °C to 50 °C

Weighing Characteristics

Volumes	Maximum net capacity	Resolution	Accuracy
50 L	60 kg	20 g	60 g
100 L	110 kg	20 g	60 g
200 L	220 kg	20 g	60 g
400 L	450 kg	50 g	150 g
650 L	750 kg	50 g	150 g
1,000 L	1,100 kg	100 g	300 g

Dimensions & Weight

Palletank® for Mixing

Volume	Dimensions (approx.) W × D × H	Weight
50 L	785 × 705 × 989 mm	78 kg
100 L	785 × 705 × 1,094 mm	86 kg
200 L	785 × 705 × 1,194 mm	105 kg
400 L	1,031 × 873 × 1,344 mm	142 kg
650 L	1,181 × 1,008 × 1,454 mm	175 kg
1,000 L	1,296 × 1,157 × 1,654 mm	256 kg

Palletank® for Mixing with Weighing

Volume	Dimensions (approx.) W × D × H	Weight
50 L	878 × 705 × 1,018 mm	81 kg
100 L	921 × 705 × 1,115 mm	90 kg
200 L	981 × 705 × 1,194 mm	108 kg
400 L	1,159 × 873 × 1,344 mm	145 kg
650 L	1,311 × 1,008 × 1,454 mm	178 kg
1,000 L	1,426 × 1,157 × 1,654 mm	259 kg

2.2 Palletank® Jacketed

Description	Volumes	Technical Specification	
Version		PED (for Europe, Asia and NEMA)	ASME (for North America)
Volumes		50 L | 100 L | 200 L | 400 L | 650 L | 1,000 L	
Main construction materials	50 L to 1,000 L	Stainless Steel 304L, Perlit Balls (insulation)	Stainless Steel 304L, Foam Glass and Ceramic Fiber (insulation)
Surface finish	50 L to 1,000 L	Acid cleaned, stainless steel bead blasted and passivated	
Door	50 L | 100 L 200 L | 400 L 650 L to 1,000 L	No door Front insulated hinged door Front insulated hinged doors	
Bag tubing gate	50 L to 1,000 L	Hinged PTFE bottom door	Hinged UHMW bottom door
Port	50 L to 1,000 L	Railed port for drive unit coupling	
Mobility	50 L to 1,000 L	Mounted on stainless cart with four clean room wheels and push handles	
Operating temperature	50 L to 1,000 L	0 °C to 50 °C	
Inlet pressure maximum	50 L to 1,000 L	6 bar	10 bar
Pressure loss maximum	50 L to 1,000 L	0,4 bar	0,4 bar
Test pressure	50 L to 1,000 L	9 bar	13 bars
Compliance	50 L to 1,000 L	PED	Heat exchanger ASME certified From heat exchanger : designed and build under ASME code
Insulated	50 L to 1,000 L	On all sides, the bottom and the lids	
Jacketed	50 L and 100 L 200 L to 1,000 L	4 sides and bottom 3 sides and bottom	
Inlet | outlet of heat transfer fluid	50 L to 1,000 L	DN20 with flange nozzles 50.5 mm Ball valve DN20 PN64	Connector Male NPT

Dimensions & Weight

Palletank® for Mixing Jacketed
PED Version (for Europe, Asia and NEMA)

Volume	Dimensions (approx.) W × D × H	Weight
50 L	847 × 817 × 1,045 mm	118 kg
100 L	878 × 817 × 1,150 mm	178 kg
200 L	949 × 969 × 1,250 mm	238 kg
400 L	1,158 × 1,186 × 1,399 mm	347 kg
650 L	1,242 × 1,319 × 1,509 mm	456 kg
1,000 L	1,376 × 1,435 × 1,710 mm	592 kg

Palletank® for Mixing Jacketed
ASME Version (North America)

Volume	Dimensions (approx.) W × D × H	Weight
50 L	847 × 817 × 1,045 mm	118 kg
100 L	878 × 817 × 1,150 mm	178 kg
200 L	949 × 969 × 1,250 mm	238 kg
400 L	1,158 × 1,186 × 1,399 mm	347 kg
650 L	1,242 × 1,319 × 1,509 mm	456 kg
1,000 L	1,376 × 1,435 × 1,710 mm	592 kg

Palletank® for Mixing Jacketed with Weighing PED Version (for Europe, Asia and NEMA)

Volume	Dimensions (approx.) W × D × H	Weight
50 L	970 × 817 × 1,058 mm	121 kg
100 L	1,013 × 817 × 1,150 mm	181 kg
200 L	1,112 × 969 × 1,250 mm	241 kg
400 L	1,287 × 1,186 × 1,399 mm	350 kg
650 L	1,412 × 1,319 × 1,509 mm	459 kg
1,000 L	1,511 × 1,435 × 1,710 mm	595 kg

Palletank® for Mixing Jacketed with Weighing ASME Version (North America)

Volume	Dimensions (approx.) W × D × H	Weight
50 L	970 × 817 × 1,058 mm	121 kg
100 L	1,013 × 817 × 1,150 mm	181 kg
200 L	1,112 × 969 × 1,250 mm	241 kg
400 L	1,287 × 1,186 × 1,399 mm	350 kg
650 L	1,412 × 1,319 × 1,509 mm	459 kg
1,000 L	1,511 × 1,435 × 1,710 mm	595 kg

2.3 Powder Bag Holders

Description	Powder bag holder 50 L to 200 L	Powder bag holder 400 L to 1,000 L
Construction material	Stainless Steel 304 and Nylon	Stainless Steel 304 and Nylon
Surface finish	Bead Blasted	Bead Blasted
Dimensions	660 × 1,360 mm	960 × 1,360 mm
Weight	14 kg	16 kg
Height above Palletank®	1,349 mm	1,349 mm
Filling weight, maximum	30 kg	30 kg
Ambient Conditions	+2 °C – +30 °C	+2 °C – +30 °C

2.4 Tubing Holder

Description	Type	Outer tube diameter	Material	Surface finish	Dimensions	Weight
Tubing Holder Single ⅝"	Single	⅝"	Stainless Steel 304 and TPE	Bead Blasted	139 × 68 mm	423 g
Tubing Holder Twin ⅝"	Twin	⅝"	Stainless Steel 304 and TPE	Bead Blasted	150 × 113 mm	465 g
Tubing Holder Triple ⅝"	Triple	⅝"	Stainless Steel 304 and TPE	Bead Blasted	150 × 158 mm	506 g
Tubing Holder Quattro ⅝"	Quattro	⅝"	Stainless Steel 304 and TPE	Bead Blasted	150 × 205 mm	546 g
Tubing Holder Single ¾"	Single	¾"	Stainless Steel 304 and TPE	Bead Blasted	139 × 77 mm	427 g
Tubing Holder Twin ¾"	Twin	¾"	Stainless Steel 304 and TPE	Bead Blasted	150 × 132 mm	474 g
Tubing Holder Triple ¾"	Triple	¾"	Stainless Steel 304 and TPE	Bead Blasted	150 × 188 mm	518 g
Tubing Holder Quattro ¾"	Quattro	¾"	Stainless Steel 304 and TPE	Bead Blasted	150 × 243 mm	559 g
Tubing Holder Single 1"	Single	1"	Stainless Steel 304 and TPE	Bead Blasted	139 × 86 mm	434 g
Tubing Holder Twin 1"	Twin	1"	Stainless Steel 304 and TPE	Bead Blasted	160 × 151 mm	510 g
Tubing Holder Triple 1"	Triple	1"	Stainless Steel 304 and TPE	Bead Blasted	160 × 216 mm	571 g
Tubing Holder Quattro 1"	Quattro	1"	Stainless Steel 304 and TPE	Bead Blasted	160 × 281 mm	626 g
Tubing Holder Single 1⅛"	Single	1⅛"	Stainless Steel 304 and TPE	Bead Blasted	146 × 86 mm	445 g
Tubing Holder Twin 1⅛"	Twin	1⅛"	Stainless Steel 304 and TPE	Bead Blasted	160 × 151 mm	510 g
Tubing Holder Triple 1⅛"	Triple	1⅛"	Stainless Steel 304 and TPE	Bead Blasted	160 × 216 mm	570 g
Tubing Holder Quattro 1⅛"	Quattro	1⅛"	Stainless Steel 304 and TPE	Bead Blasted	160 × 281 mm	627 g
Tubing Holder Single 1⅜"	Single	1⅜"	Stainless Steel 304 and TPE	Bead Blasted	156 × 89 mm	454 g
Tubing Holder Twin 1⅜"	Twin	1⅜"	Stainless Steel 304 and TPE	Bead Blasted	171 × 157 mm	527 g
Tubing Holder Triple 1⅜"	Triple	1⅜"	Stainless Steel 304 and TPE	Bead Blasted	171 × 225 mm	595 g
Tubing Holder Quattro 1⅜"	Quattro	1⅜"	Stainless Steel 304 and TPE	Bead Blasted	171 × 293 mm	657 g

2.5 Filter Holder

Description	Type	Filter diameter	Material	Surface finish	Dimensions	Weight
Filter Holder Short 55 mm	Short	55 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 55 mm	596 g
Filter Holder Long 55 mm	Long	55 mm	Stainless Steel 304 and TPE	Bead Blasted	500 × 55 mm	1519 g
Filter Holder Short 75 mm	Short	75 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 75 mm	672 g
Filter Holder Long 75 mm	Long	75 mm	Stainless Steel 304 and TPE	Bead Blasted	500 × 75 mm	1596 g
Filter Holder Short 100 mm	Short	100 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 100 mm	735 g
Filter Holder Long 100 mm	Long	100 mm	Stainless Steel 304 and TPE	Bead Blasted	500 × 100 mm	1658 g
FT HOLDER SHORT H 75 mm	Short	75 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 75 mm	672 g
FT HOLDER SHORT H 55 mm	Short	55 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 55 mm	596 g
FT HOLDER SHORT H 100 mm	Short	100 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 100 mm	735 g

2.6 pH Reader Holder and pH Bag Holder

Description	Material	Surface finish	Dimensions	Weight
Palletank® for Mixing pH Reader Holder	Stainless Steel 304 and elastomer	Bead Blasted	245 × 170 × 181 mm	1,499 g
Palletank® for Mixing pH Bag Holder	Stainless Steel 304 and elastomer	Bead Blasted	160 × 181 × 212 mm	1,519 g

3. LevMixer® Drive Unit

The LevMixer® drive unit generates the levitation and rotation of the single-use magnetic impeller without surface contact. The drive unit is mobile, cart-mounted and designed to interface with Palletank® for Mixing of different types and volumes.

3. LevMixer® Drive Unit

Footprint in mm (inches) W × L × H	Collapsed configuration: 407 × 1,118 × 915 mm (16 × 44 × 36 in) Expanded configuration: 407 × 1,311 × 915 mm (16 × 51.6 × 36 in)
Weight	123 lbs (56 kg)
Control box, cart and mixer enclosure material	304 L stainless steel
Control box, cart and mixer enclosure surface finish	At least 35 µin. Ra | 0.89 µm Ra
Control box ingress rating	IP 65
Enclosure ingress rating	IP 23
Voltage	100 – 230 VAC, 50 | 60 Hz
Input wattage	Less than 350 W
Amperage	100 V 3.0 A; 110 V 2.5 A; 230 V 1.5 A
Voltage fluctuation	+/- 10%
Altitude rating	1,000 m (3,280 ft)

3. LevMixer® Drive Unit

Max humidity	85%, avoid condensation
Ambient temperature	4 – 40 °C
Motor horsepower	⅛ hp
Power cord length	6 m (20 ft)
E-stop (present, yes | no, location)	Yes, face of control box
Min and max impeller speed	20 to 210 RPM
Connections for remote output | control	TURCK RSFPV61, RSFPV579
Functions available from remote control panel	Motor – start, stop Speed – adjustment, indication Alarm – indication Mode of control (remote | local) – indication
Signal type(s) for remote output | control	Impeller speed out 4 – 20 mA, motor control in 0 – 10 V_{DC}, discrete I | O signals relay contact type
Mixer charge time	35 minutes
Operator interface type	Touchscreen PLC
Method for RPM measurement	Direct measurement of impeller speed via non-contact magnetic sensor
Noise level at operator position	67 dB
Mobility	Mounted on stainless steel cart with four clean-room wheels and push handles 2 × swivel (front), 2 × stationary (rear)
Wheel material	Polyurethane
Recipe storage	Up to 10 recipes can be stored
Password protection	Operator, supervisor, maintenance levels
CE mark	Compliant
UL	Compliant

Ordering Information

1. Flexsafe® Bags for LevMixer®

Part Number	Volume	Description	Qty/Box
FMS301047	50 L	STD Flexsafe® LevMixer® 50 L	1
FMS301048	100 L	STD Flexsafe® LevMixer® 100 L	1
FMS301049	200 L	STD Flexsafe® LevMixer® 200 L	2
FMS301050	400 L	STD Flexsafe® LevMixer® 400 L	2
FMS301051	650 L	STD Flexsafe® LevMixer® 650 L	1
FMS301052	1,000 L	STD Flexsafe® LevMixer® 1,000 L	1

2. Palletank® for Mixing

All Palletank® for Mixing are delivered with adaption set and clamp holder.

2.1 Palletank® for Mixing

Part Number	Description
FXC301951	Palletank® for Mixing 50 L
FXC301952	Palletank® for Mixing 100 L
FXC301953	Palletank® for Mixing 200 L
FXC301954	Palletank® for Mixing 400 L
FXC301955	Palletank® for Mixing 650 L
FXC301956	Palletank® for Mixing 1,000 L

Palletank® for Mixing with Weighing

Part Number	Description
FXC301962	Palletank® for Mixing with Weighing 50 L
FXC301963	Palletank® for Mixing with Weighing 100 L
FXC301964	Palletank® for Mixing with Weighing 200 L
FXC301965	Palletank® for Mixing with Weighing 400 L
FXC301966	Palletank® for Mixing with Weighing 650 L
FXC301967	Palletank® for Mixing with Weighing 1,000 L

2.2 Palletank® for Mixing Jacketed

Palletank® for Mixing Jacketed PED (for Europe, Asia and NEMA)

Part Number	Description
FXC301930	Palletank® for Mixing Jacketed 50 L PED
FXC301931	Palletank® for Mixing Jacketed 100 L PED
FXC301932	Palletank® for Mixing Jacketed 200 L PED
FXC301933	Palletank® for Mixing Jacketed 400 L PED
FXC301934	Palletank® for Mixing Jacketed 650 L PED
FXC301935	Palletank® for Mixing Jacketed 1,000 L PED

Palletank® for Mixing Jacketed with Weighing PED (for Europe, Asia and NEMA)

Part Number	Description
FXC301940	Palletank® for Mixing Jacketed with Weighing 50 L PED
FXC301941	Palletank® for Mixing Jacketed with Weighing 100 L PED
FXC301942	Palletank® for Mixing Jacketed with Weighing 200 L PED
FXC301943	Palletank® for Mixing Jacketed with Weighing 400 L PED
FXC301944	Palletank® for Mixing Jacketed with Weighing 650 L PED
FXC301945	Palletank® for Mixing Jacketed with Weighing 1,000 L PED

Palletank® for Mixing Jacketed ASME U (North America)

Part Number	Description
FXC301994	Palletank® for Mixing Jacketed 50 L ASME U
FXC301995	Palletank® for Mixing Jacketed 100 L ASME U
FXC301996	Palletank® for Mixing Jacketed 200 L ASME U
FXC301997	Palletank® for Mixing Jacketed 400 L ASME U
FXC301998	Palletank® for Mixing Jacketed 650 L ASME U
FXC301999	Palletank® for Mixing Jacketed 1,000 L ASME U

Palletank® for Mixing Jacketed with Weighing ASME U (North America)

Part Number	Description
FXC302004	Palletank® for Mixing Jacketed with Weighing 50 L ASME U
FXC302005	Palletank® for Mixing Jacketed with Weighing 100 L ASME U
FXC302006	Palletank® for Mixing Jacketed with Weighing 200 L ASME U
FXC302007	Palletank® for Mixing Jacketed with Weighing 400 L ASME U
FXC302008	Palletank® for Mixing Jacketed with Weighing 650 L ASME U
FXC302009	Palletank® for Mixing Jacketed with Weighing 1,000 L ASME U

2.3 Powder Bag Holders

Part Number	Description
FXA304216	Powder bag holder 50 L to 200 L
FXA304217	Powder bag holder 400 L to 1,000 L

2.4 Tubing Holder

Part Number	Description
FXC301562	Tubing Holder Single ⅝"
FXC301563	Tubing Holder Twin ⅝"
FXC301564	Tubing Holder Triple ⅝"
FXC301565	Tubing Holder Quattro ⅝"
FXC301566	Tubing Holder Single ¾"
FXC301567	Tubing Holder Twin ¾"
FXC301568	Tubing Holder Triple ¾"
FXC301569	Tubing Holder Quattro ¾"
FXC301570	Tubing Holder Single 1"
FXC301571	Tubing Holder Twin 1"
FXC301572	Tubing Holder Triple 1"
FXC301573	Tubing Holder Quattro 1"
FXC301574	Tubing Holder Single 1⅛"
FXC301575	Tubing Holder Twin 1⅛"
FXC301576	Tubing Holder Triple 1⅛"
FXC301577	Tubing Holder Quattro 1⅛"
FXC301578	Tubing Holder Single 1⅜"
FXC301579	Tubing Holder Twin 1⅜"
FXC301580	Tubing Holder Triple 1⅜"
FXC301581	Tubing Holder Quattro 1⅜"

2.5 Filter Holder

Part Number	Description
FXC301582	Filter Holder Short 55 mm
FXC301583	Filter Holder Long 55 mm
FXC301584	Filter Holder Short 75 mm
FXC301585	Filter Holder Long 75 mm
FXC301586	Filter Holder Short 100 mm
FXC301587	Filter Holder Long 100 mm
FXA304200	FT HOLDER SHORT H 75 mm
FXA304201	FT HOLDER SHORT H 55 mm
FXA304202	FT HOLDER SHORT H 100 mm

2.6 pH Reader Holder and pH Bag Holder

Part Number	Description
FXA304214	Palletank® for Mixing pH Reader Holder
FXA304215	Palletank® for Mixing pH Bag Holder

3. LevMixer® Drive Unit

Part Number	Description
LT-DBTL300	Superconducting drive machine on cart with universal latch for 8", 15" and 23" ports. Control panel (100–230 V) and lifting mechanism on handle and welded body. 304 L stainless steel with 35 µin. Ra | 0.89 µm Ra surface finish. Includes tool box with accessories.

3.1 Accessories for LevMixer® Drive Unit

Part Number	Description
LT-SVSP402	Remote control cable – Analog I | O Cable, 6 m (20 ft)
LT-SVSP403	Remote control cable – Digital I | O Cable, 6 m (20 ft)