LeSplit® Split

Data Driver

User Guide

Shanghai LePure Biotech Co., Ltd.

Catalogue

1. Product introduction

The LeSplitmixer is a disposable split-body mixing and driving vehicle consisting of a stainless steel shell, a magnetic stirring motor, and a control system. It is used in conjunction with the LeKrius disposable mixing bag to achieve liquid-liquid or solid-liquid mixing. The equipment adopts a modular design, which can be flexibly assembled and disassembled according to needs. This design allows the vehicle to adapt to different working conditions and scenarios, and also facilitates maintenance and upgrades.

2. Product application

- Buffer preparation
- Media preparation
- Mixing of purified intermediate products
- pH adjustment
- Preparation of semi-finished products
- Vaccine adjuvant processing
- Mixing before filling

3. Product features

- The mixing system and control unit are integrated into a drive car, which is separate from the tank body.
- Various sensor plug-in interfaces are designed on the drive car, which can autonomously select functional modules for connection.
- It can realize one control cabinet controlling the connection of tanks with different specifications.
- Non-contact magnetic coupling drive, clean permanent magnet body is sealed by injection molding.,

- Built-in lifting motor, magnetic cylinder can be adjusted up and down.
- Multiple types of impellers are optional.
- It meets functions such as access control, audit tracking, data recording, batch reporting, etc. Complies with 21CFRpart11
- It can be connected to SCADA, MES and other central control systems, with reserved Ethernet interface and support for TCP/IP protocol.

4. Compliance

The LeSplitmixer disposable split-body mixing drive unit complies with the CE standards in European Union countries.

- Machinery Directive(MD)2006/42/EC
- Low Voltage Directive (LVD) 2014/35/EU
- EN ISO12100:2010
- EN 60204-1:2006+A1:2009+AC:2010
- CE
- EN ISO 9001

5. Technical Information

Description	Specification
Housing material	SS304
Surface polishing	Drawbench Ra≤0.8μm
Fit volume	50L-1000L
Stirring motor	Panasonic
Stirring speed	0-250rpm
Power & power	220V±10%&900W
Operating temperature	0-60℃
HMI	Siemens 12" IPC
Control system	Siemens CPU+PLC
Data interface	RJ45/USB
Communication protocol	Supports TCP/IP protocol

6. Equipment Ordering and Selection

Optional module

	Integrated function module (optional)							
Name	pH	CT	DO	TT	weigh	Print	Peristaltic pump	TCU
Module branding	Hamilton	Hamilton	Hamilton	GTAM	WIKA	weihuang	Masterflex	LAUDA
	Mettler	Mettler	Mettler	Labom	Mettler	NA	Watson-Marlow	LEPURE
Module selection	YES ☐	YES ☐	YES ☐	YES ☐	YES ☐	YES ☐	YES ☐	YES ☐
	NO ☐	NO ☐	NO ☐	NO ☐	NO ☐	NO ☐	NO ☐	NO ☐

7. Standard ordering information

Stock code	Device family	voltage	pH	TT	weigh	CT	HMI	print
BMCSZ000	Split type mixing control truck	220V± 10%	√	√	√	√	√	√
BMCSZ001					√		√	√

8. Power plug selection

Plug Information:

☐	EU	
☐	US	
☐	UK	
☐	JP	

9. System optional sensor function parameters

Weigh		The equipment can be equipped with METTLER or equivalent brand weigh module, which can display weighing data in real time, calibrate the weighing module online, and the control system can fully automatic data recording and storage. Weighing range:

		0~120%*FS, weighing accuracy: ±0.3%.
Temperature sensor		Temperature sensor, real-time display of temperature value on the display, control system can fully automatic data recording and storage. Temperature measurement range: 0~60 °C, accuracy: ±0.5 °C.
pH		pH sensor with automatic temperature compensation, real-time pH value display on the display, sensor calibration, and fully automatic data logging and storage by the control system. pH measurement range: 0~14, accuracy: ±0.05.
CT		The equipment can be equipped with a conductivity sensor, including automatic temperature compensation, the conductivity value can be displayed in real time on the display, the sensor can be calibrated online, and the control system can fully automatic data recording and storage. Conductance measurement range: 1us-300mS/cm, accuracy: ±5%.
DO		The equipment can be equipped with a conductivity sensor, including automatic temperature compensation, the conductivity value can be displayed in real time on the display, the sensor can be calibrated online, and the

		control system can fully automatic data recording and storage. Measuring range: 0~100%*Sat (METTLER)/0~300%*SAT (Hamilton), accuracy: ±1%+6 ppb (METTLER) or ±1% (Hamilton).
Printers		Online micro non-thermal printer that can print weight, temperature, pH and other monitoring data in real time.
Peristaltic pump (acid and alkali regulation)		1 or 2 peristaltic pumps are available on request for the transfer of acids and/or lyes, and the peristaltic pump is controlled by a variable speed of 8 / 15 knots via the control system for precise pH adjustment

10. Description of the control system

The control system mainly has Siemens CPU and 12-inch IPC industrial computer components of the control system platform, the control system has its own separate control cabinet, the cabinet material is 304 stainless steel, protection grade IP54, the cabinet is equipped with filter plates, etc. The CPU and its accessories and communication modules are installed on the internal mounting board of the cabinet, and the IPC will be installed above the front door of the cabinet and the position of operation. The control system can control all functions, can fully automatic data collection and storage records, with password security management, authority management, alarm function, audit trail and batch report and other functions, data

can be exported by PDF, in line with the GMP regulatory requirements of 21CFRpare11.

11. Alarm description

The control system has automatic program detection and process parameter monitoring alarm functions. When the alarm condition is triggered, the program enters the alarm phase, beeps the alarm, and pauses the operation of the device. Alarm ranges include:

- Abnormal monitoring parameters beyond the safety threshold range (speed, weight, temperature, pH, conductivity, DO)
- Power failure
- Abnormal sensor connection

12. Shipping Packaging

- Wooden box - logistics and transportation

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