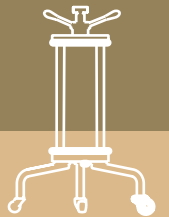




金仪盛世
JYSS BIO



TOR Su Bioreactor



TOR Single-use & Direct-axis Stirred Bioreactor

Option for Efficient and Easy Cell Culture

TOR single-use & direct-axis stirred serial bioreactor, an appliance designed based on the mixing principle for traditional bioreactor, is featured with superior performances involving both mixing culture effect of traditional stirring and single-use process unit free from cleaning and sterilization verification, and it is a highly efficient, easy-to-use and powerful cell culture platform made up of hardware, software and consumables, achieving the best cell growth, cell vitality and metabolic process, and covering the scale ranging from 50L to 2000L.



Application Areas

TOR single-use & straight-axis stirred bioreactor is developed and tested for mammalian cell culture, and is suitable for areas of biological products involving the antibody, vaccine, gene and cell therapy. Typical applications include:

- Suspension cell and microcarrier culture
- Process development
- Process amplification
- Seed amplification of large bioreactors
- production of clinical trial samples
- Production of pilot scale
- cGMP scale production



Product Features

Mixed axial flow, excellent materials transfer effects and high-quality accessories secure stable & convenient system operation and modular design, and support customer customization

Pressure control function provides safety protection

Three-level permission and audit trail are offered, and complete report for electronic data is provided for easy transmission and storage

Multiple, simple and intuitive touch screen software control functions are presented, and the feedback system logic is clear

- The top and bottom ventilation are designed with a single-use reaction bag chassis to flexibly adjust the ventilation strategy
- Complete FAT, SAT, IQ/OQ files and services are offered.

Tank Design

Mixing

Use the down-stroke agitator blade with low shear force is utilized to form axial flow, supplies in the tank are fully mixed, and cells in the culture system are kept to be in suspension to ensure full contact between cells and nutrients. The agitator blade with low shear force disperses the gas at the bottom and evenly distributes it into the culture medium to improve the gas-liquid mass transfer efficiency and meet the requirements for cell culture.

Heating and Cooling

The PT1000 sensor is connected to a double-wall jacket, and the TCU temperature control unit is connected and controlled to ensure efficient heating, cooling and solution temperature uniformity. The product is featured with temperature protection, overheat alarm and automatic heating suspension for overheating.

DO Oxygen Dissolution

The ventilation chassis with accurate positioning is provided with two modes: Ring-sparger and micro-sparger. The DO sensor supports choosing traditional optical electrode or single-use optical fiber electrode to implement online monitoring and calibration, and is flexibly switched according to process requirements

Automatic mode: The real-time control on DO value in the process is implemented. The DO sensor is linked to the air, N₂ and O₂ mass flow controllers and the mixing speed to implement closed-loop control and form an aggregate value. The system supports recording the real-time flow of gas and counting the aggregate value.

Manual Mode: N₂ and O₂ are supported to be independently controlled on the human-machine interface. The system supports recording and counting the real-time flow and aggregate value of the N₂ and O₂.

Pressure Protection

For the pressure sensor beyond the set value, the system will automatically close the mass flow controller or open the pressure relief valve to ensure that the cell culture process keeps the appropriate pressure and the TOR reaction bag is not damaged.

Online PH Monitoring

The pH sensor supports selection of the traditional digital electrode or single-use optical electrode to implement online monitoring and calibration, and pH control in the process through linkage with acid-base pump.

Automatic Mode: The pH sensor is linked to acid-base pump and CO₂ mass flow controller to implement closed-loop control and record accumulated acid-base flow

Manual Mode: The acid-base pump and CO₂ mass flow controller supports independently control on human-machine interface.

Peristaltic Pump and Weighing

Replenishment pump: replenish infusion into the reactor

Automatic Mode: The make-up pump is supported to be linked to the weighing to implement closed-loop control. When the set weight is hit, the system will automatically stop, record and count the aggregate value of the replenishment pump.

Manual Mode: The control is supported to be independently controlled on the human-machine interface in the manual mode, and the system will record and count the aggregate value of the make-up pump.

Timing Mode: The flow rate and time are supported to be recorded according to the total volume of infusion to be replenished.

Technical Parameters

Specification	50L	200L	500L	1000L	2000L
Overall dimensions of the reactor (, L×W×H, mm)mm	853*670*1940	800*1000*1115	1264*1002*2306	/	1728*1658*3868
Overall dimensions of the control cabinet (, L×W×H, mm)mm	538*629*1630	538*629*1630	538*629*1630	538*629*1630	538*629*1630
Power of the control cabinet (KW)	2	2	2.6	2.6	17
Size of TCU	450*550*650	550*650*970	650*670*1250	650*670*1250	760*650*1605
Power of TCU (KW)	2	5	7	10	20
Weight (Kg)	300	470	620	/	2620
Working volume (L)	12.5-50	50-200	125-500	250-1000	500-2000
Range of speed (rpm)	0-240	0-150	0-110	0-90	0-70
Accuracy of rotational speed control	±2 rpm				
Temperature control	Control range: Room temperature ~ 42 °C ; control accuracy: ± 0.2 °C				
pH control*	*Digital intelligent electrode, control range: 0-12; control accuracy: ± 0.02				
	Single-use optical fiber electrode, control range: 5.5-8.5; control accuracy: ± 0.1				
DO control*	*Optical intelligent electrode, control range: 0-100./, Air saturation, control accuracy ± 5%				
	Single-use optical fiber electrode, control range 0-100./, Air saturation, control accuracy: ± 5%				
Mass flow controller MFC*	Accuracy: ± 2% FS; resolution: 1ml/min				
Weight	Accuracy: C3, resolution: 0.1kg				
蠕动泵	Speed: 0-400 rpm; flow range: 0-1200ml/min				
Pressure protection	Measuring range: 0-25kpa; accuracy 0.25/FS				
Offgas heating control	Control range: Room temperature ~ 60C; control accuracy ± 0.5 °C				

TOR Single-use Straight Shaft Stirring Reaction Bag

TOR stirring reaction bags are matched with JYSS Bio series reactors with high mixing efficiency, excellent oxygen transmission and low shear force, applied to mammalian cell culture and are supported to be expanded to high cell density, microcarrier, perfusion culture and other processes. EB1596 membrane is used for the bag body, and electrode interfaces including the feed batch, pH, DO and temperature can be flexibly reserved in combination with the reactor, with the volume ranging from 50L to 200L, and up to 2000L in the future. The reaction bag will be subject to 100% integrity test, and sterilized by irradiation after double packaging to ensure the safety and stability of cell growth.



Structure of TOR Stirring Reaction Bag Product

Mixing propeller: PE+PET Materials

Paddle blade: The three-blade inclined paddle combination or three-blade inclined paddle and six-blade straight paddle combination is available

Bubbling: Big bubble or micro bubble compound type foam maker is to be selected

Electrode interface: Supported to adapt to Mettler or any other brand of traditional electrode (diameter: 12mm, length: 225 mm/220 mm in), and single-use electrode is supported to be selected.

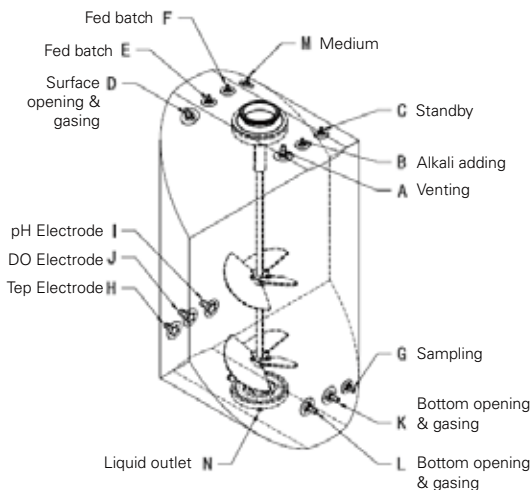
Interfaces: The locations of other line interfaces are shown in the figure and can be flexibly selected based on technological process requirements.



Aperture of Great Bubble: 0.8mm
Aperture of Micro Bubble: 150 um



Schematic Diagram for Line Interface

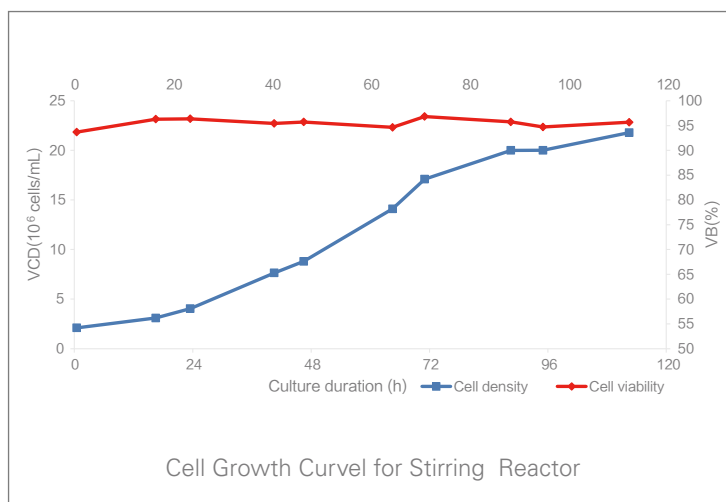


Parameters of TOR Stirring Reaction Bag Product

	50L	200L
Total volume (L)	68	200
Maximum working volume (L)	50	200
Minimum working volume (L)	12.5	50
H/D proportion	1.8	1.8
Liquid height h1 (mm)	480	783
h1/D proportion	1.3	1.34
Blade diameter d2 (mm)	143	225
d2/D proportion	0.38	0.38
Blade spacing Az (mm)	186	300
Aperture of foam maker (mm)	0.8	0.8
Hole count of foam maker	5	25
Aperture of micro of foam maker (um)	150	150
Hole count of micro of foam maker	20	100

Cell Culture Test

CHO cells are to be cultured in batches, and the cell viability is to be maintained above 95% with the maximum cell density of 2×10^7 .



Compliances and Traceabilities

Biosafety test item	Standard	Tested data
Sensitization test	ISO 10993-10	Compliant
In-vivo biological reaction	USP<88>	Compliant
In-vitro cytotoxicity	USP <87>	Compliant
Bacterial endotoxin	USP <85>	< 0.25EU/mL
Hemolysis test	ISO 10993-4	Free of hemolysis
Appearance	USP<661.2>	Compliant
Acidity-alkalinity	USP<661.2>	Compliant
Absorbance	USP<661.2>	Compliant
Total organic carbon	USP<661.2>	Compliant
Light transmittance	USP<661.2>	Compliant
Free of animal derivation		Free of animal-derived material

Physicochemical performance test item	Standard	Tested data
Tensile strength	ASTM D882	26Mpa
Elongation at break	ASTM D882	603%
Transmission rate of oxygen	ASTM D3985	1.67(cc/m ² /Day)23T ,0%RH
Transmission rate of water vapor	ASTM 1249	1.23(g/m ² /Day)38T ,90%RH
Haze	ASTM D1033	6.78%
Film thickness	/	0.33mm
Average thickness deviation	GB/T6672	1%
Thickness limit deviation	GB/T6672	0.02
Membrane contact material	/	ULDPE
Temperature tolerance	/	-80° C -70° C
Heat seal strength	YBB00122003	72N/15mm
Extractable	USP<665>	Three kinds of solvents, pH3, pH10 and 50% ethanol with excellent extraction data were used for extraction
Term of validity	ASTM F1980	Two years after irradiation



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