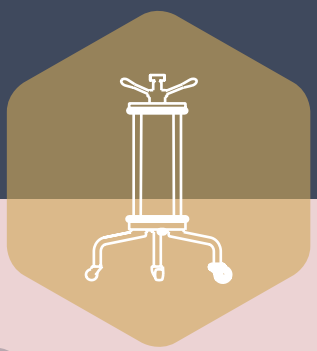
金悦盛世
JYSS BIO

GER Wave Bioreactor



Efficient and Reliable GER Wave Bioreactor

GER series wave bioreactor, a highly effective and reliable cell culture system, functionalizes mixing and dissolving oxygen through the wave oscillation mode together with optional sensor module, process automation and control software system and GER wave reaction bag. The working volume of the device is up to 25L, providing solutions for general life science research, seeding tank culture and cGMP production in the biopharmaceutical field.

Applied in producing biopharmaceuticals, vaccines, gene therapy and other products, and typical applications include:

- Suspension culture of mammalian cells, such as CHO or HEK293 cells
- Microcarrier culture of adherent cells, such as Vero
- Insect cell culture, such as Sf9 cells
- Immune cells, such as stem cells, and continuous perfusion of T cells
- Batch and fed batch culture of suspension cells

Excellent Culture Property

Precisely control the swing angle and speed, quickly mix and improve the gas mass transfer; gentle swing mode minimizes the shear force of sensitive cells; no bubbling ventilation is required for fluid exchange on the surface to avoid cell damage and application of the defoamer, making for improving cell status, cell density and production

Flexible Configuration and Convenient Operation

Compatible with reaction bags of different specifications, reducing hardware investment cost; flexible cultivation volume decreases the transfer between containers, reduces the pollution risk, and saves the working hours for transfer; replacement of different cell products avoids cross contamination, realizing the cleaning, sterilization and cleaning validation

Powerful Platform Universality

The device is applicable for culturing a majority of suspension cells and microcarriers, like mammalian cells, insect cells, cell therapy, etc; compatible with batch culture, batch feeding or continuous perfusion and other culture methods; applicable for R&D, seed culture, process amplification, and GMP commercial scale production

Accurate and Reliable Control System

Precisely control the swing angle and rotation speed, and cooperate with pH+DO sensor to provide the measurement and control of key process parameters to comprehensively monitor the cell culture process, realizing more stable and reliable cell culture process

System Composition of The Wave Bioreactor

Oscillator Module

The control system is capable of controlling the speed and angle of the winger, which is equipped with the servo motor, being durable, safe and stable.

Temperature Control

The heating film mode is adopted, the warming process is stable and uniform, and the one for two version is supported to be controlled separately.

PH Control Module

pH value in the process of real-time control

- Automatic mode: pH sensor is associated with the acid-base pump and CO_2 to achieve closed-loop control, and the cumulative acid-base flow is recorded.
- Manual mode: CO_2 gas valve, acid pump and alkali pump are supported to be independently controlled on the human-machine interface

DO Control Module

- Automatic Mode: DO value is controlled in the process in real-time manner, DO sensor is connected to Air gas valve, team gas valve and O_2 gas valve to achieve closed-loop control and form the cumulative system, the real-time flow of N_2 and O_2 is recorded, and the integrated value is counted.
- Manual Mode: Air, N_2 and O_2 are supported to be independently controlled on the human-computer interface, and the system is capable of recording and count the real-time flow and cumulative value of AIR, N_2 and O_2.

Software System

- The system supports realizing functions involving the access control and user management, electronic signature and electronic recording, audit tracking and change control, data archiving, curve analysis and data backup, alarm prompt, and can monitor six GER wave bioreactors
- The system meets requirements on computer system under GMP environment, and is in conformity with requirements of GAMP5, 21 CFR Part 11 as well as other relevant laws and regulations

Irrigation Control Unit (Optional)

The control of liquid make-up pump and harvest pump is divided into two states

- Timing Control: By setting the flow rate and timing time per minute, the liquid make-up pump automatically implements the fluid infusion to the reactor
- Manual status: The device supports independently controlling the human-machine interface, and the system supports recording and counting the cumulative value of the infusion pump.
- The infusion pump and weighing unit are associated to realize automatic infusion with adjustable flow.

Technical Parameters

Item	50L wave bioreactor
Total volume (L)	50L
Maximum working volume (L)	25L
Minimum working volume (L)	5L
Range of speed (rpm)	2-35 rpm
Control accuracy of speed	±1 rpm
Angle range (°)	2-12°
Angle control accuracy	±0.5°
pH control	Single-use optical electrode with a control range of 5.5-8.5 and control accuracy of ± 0.1
DO control	Single-use optical electrode with the control range of 0-100 %, air saturation and control accuracy of ± 5%
DO monitoring	Single-use optical electrode, monitoring range of 0-100%, pure oxygen and measurement accuracy of ± 2%
Temperature control	Range of control: Room temperature to 50 ° C, control accuracy of ± 0.2 ° C
Temperature control	PT1000, measuring range of 50 ～ 300 ° C, and measuring accuracy of ± 0.2 ° C
Weighting	Measuring range of 0-100kg, measuring accuracy of ± 1%
Mass flow controller for CO2 and N2	Maximum range of flowmeter: 2L Accuracy: ± 2% of full range
Mass flow controller for air and O2 pump flow (ml/min)	Maximum range of flowmeter:5L Accuracy: ± 2% of full range
Peristaltic pump flow (ml/min)	Wall thickness in 1.6mm

Order Information

Article Number	Configuration Description
WAV-0050SA-01	50L wave bioreactor, control host & software system
WAV-0050SB-01	50L wave bioreactor, control host & software system, weighing
WAV-0050SC-01	50L wave bioreactor, control host & software system, integrated pH module
WAV-0050SD-01	50L wave bioreactor, control host & software system, integrated DO module
WAV-0050SE-01	50L wave bioreactor, control host & software system, integrated pH module, DO module
WAV-0050SF-01	50L wave bioreactor, control host & software system, integrated pH module, DO module, weighting
WAV-0050SP-01	Peristaltic pump

GER Wave Culture Bag

GE culture bag is used together with the GER reactor during the scale-up process, JYSS EB 1596 membrane materials are used in GER series culture bags, coinciding with culture bags of production scale, and the bags are sterilized by gamma irradiation after being packed.

Tough and Safe EB1596 membrane

- Extraordinary air tightness, toughness and puncture resistance ensure the integrity of bags
- Chemical inertness of the liquid contact layer minimizes dissolved matter and precipitates
- USP Class VI (USP<87>, USP<88>, and USP<661> compliant)
- No animal-derived ingredient is found

Excellent Product Performance

- The proven EB1596 membrane material is applicable for cell culture
- The integrity testing of the bag body fully reduces the risk of use
- The proven sterile gas filter ensures that the medium is free from contamination

Quality Assurance

- JYSS GER wave type culture bag quality management system is in conformity with ISO standard, refer to ISO, USP, ASTM, GMP, EP, YBB or any other domestic or foreign regulation for design, manufacturing and sterilization process. Pursuant to the ISO 11137 standard, sterility guarantee level within the warranty period hits 10-6, the particulate matter standard is in compliance with USP<788>

Flexible Configuration

- GER culture bag is applicable for the culture volume in 25L or below, including basic model and electrode model, and the electrode model is supported to be customized as pH electrode or DO electrode
- Customized according to the wave bioreactor used by the customer

Supply Security

- JYSS applies self-owned membrane material EB1596, sets up the production base with standardized processes, and coordinates with strict supplier management and plans based on customer requirements to meet customers' requirements on high-quality products and timely and stable supply

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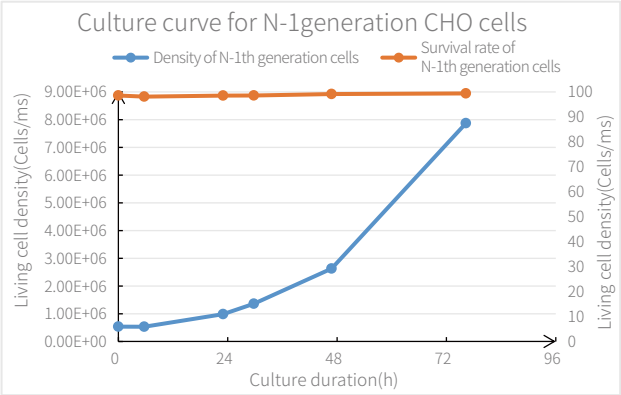
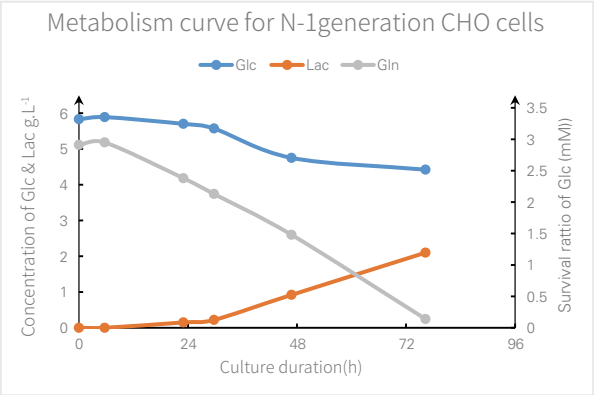
Cell Culture Data

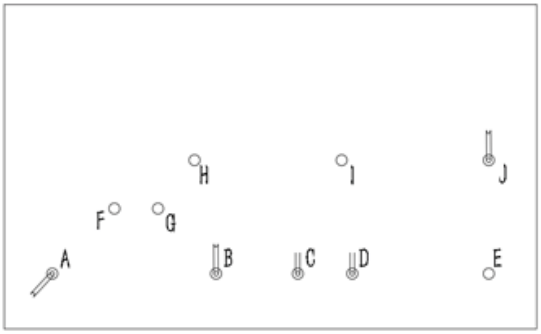


Growth curve for N-1th generation cells in GER wave bioreactor



Metabolism curve for N-1th generation cells in GER wave bioreactor

Order Information



Schematic Diagram for the 50L Wave Culture Bag

A: 1/4 * 7/16 welded pipe (1000mm), quick connector
B: 1/8 * 1/4 welded pipe (100mm) Luer tape
C: 1/8 * 1/welded pipe (100 mm) Luer tape
D: Needle less sampling, female Luer tape
E: 1/4 * 7/16 welded pipe (1000mm), quick connector
F: 1/4 * 7/16 silicone tube, gas filter
G: 1/4 * 7/16 silicone rubber tube, gas filter, external one-way check valve
H: Needle less sampling, female Luer tape
I: DO sensor
J: PH sensor

Article No.	Working Volume	Configuration Description
GER-0050L-001-A2B	25L	50L wave culture bag
GER-0050L-002-A2B	25L	50L wave culture bag, including pH and DO electrode module
GER-0020L-001-A2B	10L	50L wave culture bag
GER-0020L-002-A2B	10L	50L wave culture bag, including pH and DO electrode module

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