Limitless Bioprocessing™

OmniBRx® BIOTECHNOLOGIES

CellBRx®

Universal solution for most efficient adherent cell culture processing with ultimate efficiency and scalability

CellBRx® 0.5L

CellBRx® 5L

CellBRx® 50L/200L

www.omnibrx.com

IT'S TIME TO UPGRADE YOUR CELL CULTURE TECHNIQUE TO THE NEXT LEVEL OF BIOPROCESSING

Single-use bioreactors for intensified bioprocessing

Highlight and Benefits

- Compact high-cell-density, Dynamic bed bioreactor provides significant increase in volumetric productivity vs. traditional stirred tanks and packed bed bioreactors
- Process simplification, from pre-culture to final product
- The first fully efficient & perfusion integrated, single-use bioreactor (with pre-installed calibrated probes)
- Straightforward implementation for faster process development
- Linear scalability from R & D to manufacturing
- Dramatic decrease in operational costs and capital investments

OVERVIEW

The CellBRx bioreactors are the first proud member of OmniBRx biotechnologies' single-use bioreactor family. They are the world's first fully integrated perfusion driven, high cell density bioreactors designed to simplify adherent cell culture processes by combining the advantages of single-use technologies with the benefits of a dynamic bed reactor technology. The compact system, designed for quick implementation and ease-of-use, represents a new generation of rigid wall single-use bioreactors. Central to the CellBRx bioreactor technology is the use of a compact rotating dynamic bed design, filled with custom disc shaped macrocarriers. This matrix discs are made of medical grade non-woven polyester microfibers (USP Class VI, ISO 10993 certifications) and provides surface area up to 1500 m^2 available for cell growth in 200L bioreactor system. This surface area is equivalent of 17,647 Roller Bottles (850 cm^2 each).

CellBRx bioreactors are provided with pre-packed and custom treated macrocarriers in support matrix. It alleviates delicate and time-consuming manual operations, reducing the overall process time and making the cell culture process more robust. With biomass multiplication occurring in the dynamic-bed support matrix, CellBRx bioreactors can be inoculated at low cell densities. Manual operations and associated costs are greatly reduced, because of process simplification. Magnetically driven rotations of Discs coupled with curved vanes in Dynamic Bed reactors ensures nutritional homogeneity and significantly lower mixing time.

Dual integrated aeration systems i.e. purging gases in culture vessel overlay space and gas exchanger, efficiently support gaseous requirements of the cultures without sparging of gases directly in culture medium and there by assures Stress-Free culture of sensitive cells while maintaining high KLa the in the bioreactor. As the cells are immobilized in the dynamic-bed matrix during perfusion processing, no centrifugation or filtration is needed to clarify the harvest broth. This benefit further simplifies and reduce downstream processing steps. Culture parameter control is automatic and integrated via single-use sensors for pH, dissolved oxygen, temperature, glucose(optional), lactate(optional) etc. Aeration and agitation monitoring and controls are also included. To alleviate the bottlenecks of large scale stem cell culture technologies, the CellBRx bioreactors offer the unique advantage of healthy cell recovery at larger scale using simple cell dissociation techniques.

APPLICATIONS OF CellBRx BIOREACTORS

- **Biologics Manufacturing (mAb's, Biosimilars, Rec. Therapeutics etc.)**
- **Tissue Engineering**
- **Stem Cell Therapy**
- **Human Genetics And Gene Therapy**
- **Vaccine Production**

FEATURES

- Integrated mixing system for evenly-distributed media circulation and low shear stress
- Specially treated cell carriers specifically adapted to variety of adherent cell cultures
- Unique DBR technology to ensure efficient mixing and homogeneity
- Single-use bioreactor made from USP Class VI and ISO 10993 approved rigid plastic to ensure process reliability
- Modular size of dynamic bed from 0.5 L to 200 L – offering several customized configurations at small and large scale
- Completely single-use closed bioreactor from vessel to sensor for sterility and contamination risk reduction
- Ensured reproducibility and traceability of cell cultures by monitoring and control of culture parameters including pH, DO, temperature, glucose, biomass etc.
- Designed for use in a complete closed system from seeding to harvest
- Processing flexibility with reduction of numbers of operations, complexity and risks related to operations (e.g. cell seeding, medium exchange, harvest)

OmniBRx® BIOTECHNOLOGIES

CellBRx® 50L/200L PRODUCTION BIOREACTORS

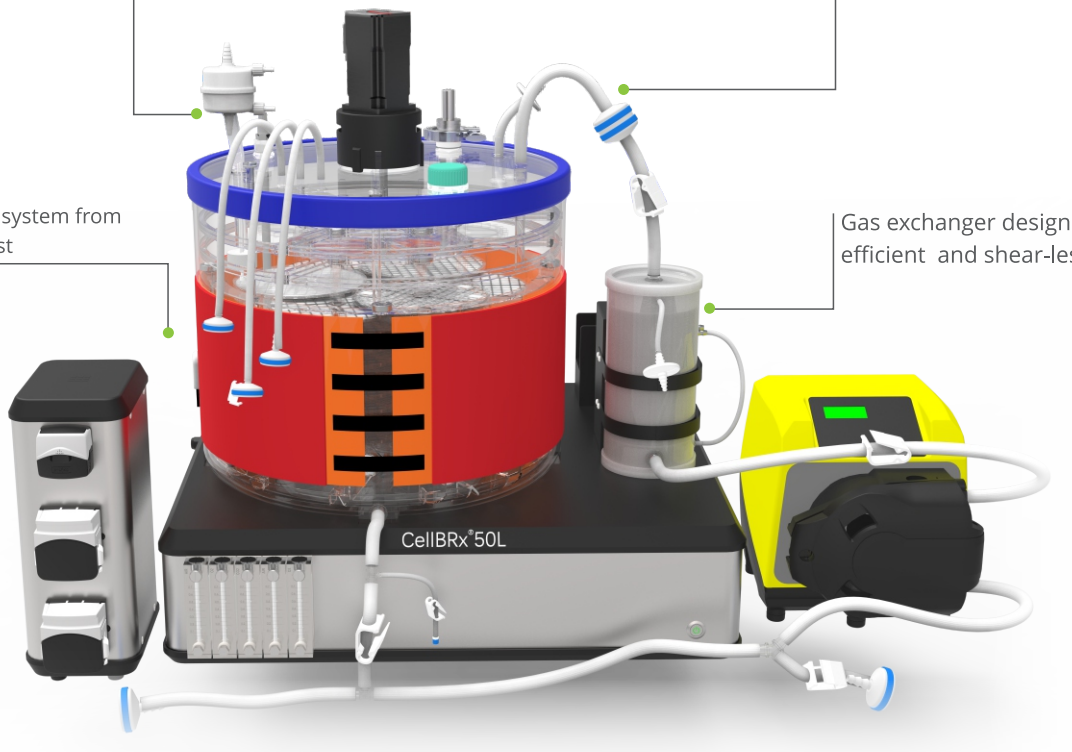
Designed to promise modularity and flexibility for multiple product manufacturing

Small facility footprints saves lot of capital investments

Intuitive process control system with perfusion logic integrated

Complete closed system from seeding to harvest

Gas exchanger designed for efficient and shear-less gas transfer



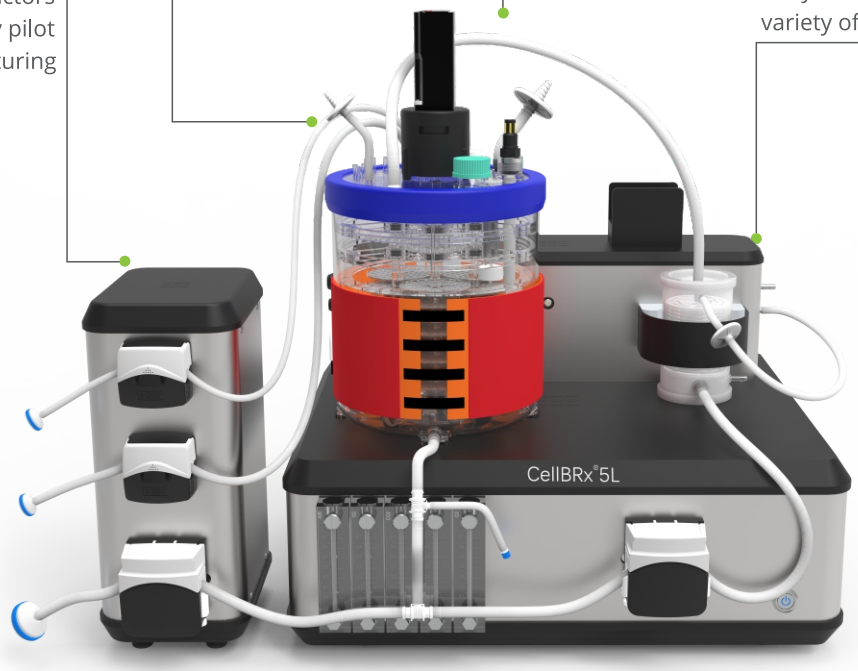
CellBRx® 5L
PILOT SCALE BIOREACTORS

Integrated mixing system for evenly-distributed media circulation

Pre-packed and custom treated macrocarriers in DBR support matrix

High cell density bioreactors designed to simplify pilot scale biomanufacturing

Truly universal and support wide variety of adherent cell lines



OmniBRx® BIOTECHNOLOGIES

CellBRx® 0.5 L
R&D SCALE BIOREACTORS

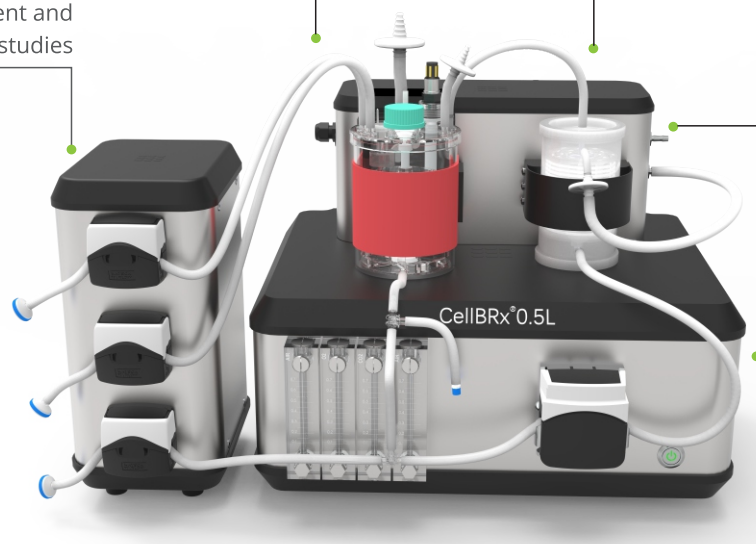
Independent process control and perfusion integration for each mini bioreactor

Linear scalability and Modular size of dynamic bed from 0.5 L to 200 L

Ensured reproducibility and traceability of cell cultures

Multiple miniscale bioreactors for rapid process development and characterization studies

Pre-sterilized, ready to use bioreactors



PERFORMANCE

Preserves the Standard Cell Environment

As in Roller bottles, T-Flasks and multi-tray stacks, cells adhere and grow on specially treated and hydrophilized cell carriers in Disc-form and are harvested using a cell dissociation treatments. With the unique Dynamic Bed Reactor (DBR) Technology, the culture support matrix maintains the same environment as roller bottles or multi-tray stacks, and enables implementation of a processes easily-adapted from these traditional methods.

Cell Culture Parameters Monitoring and control

CellBRx Bioreactors has in-built dedicated sensor ports for optical noninvasive measurement of pH and dissolved oxygen (% DO). The determination of pH and DO are based upon the principle of fluorescence to eliminate contamination risks. Depending on the DO and pH measurement, gas regulation is activated via the controller as per the users' requirements. Temperature is monitored via a PT100 sensor installed in the bioreactor vessel. Precise temperature control is provided by high quality silicon heater as Heating element and chilled water circulation through Cooling fingers. Each measure (pH, DO and temp) is associated with an alarm.

Aeration System

Gas purging in culture vessel overlay space and gas exchanger occurs depending on pH and DO control limits set by the users. Gas flow rates are accurately controlled and monitored via dedicated Mass Flow Controllers. The gas coming from the controller ports enters via the “gas in” filter of the culture vessel and gas exchanger. The gas inlet and outlet ports include pre-installed hydrophobic aeration filters. This combined aeration system efficiently support gaseous requirements of the cultures without sparging of gases directly in culture medium and there by assure Stress-Free culture of sensitive cells.

Homogenization by Medium Circulation

Medium circulation is coupled with the agitation and aeration system which depends on pH and DO control. The medium could also circulate in the bioreactor independently of gas aeration according to users' requirements. Disc rotations coupled with curved vanes rotation in Dynamic Bed reactors ensure nutritional homogeneity and significantly lower mixing time. During perfusion culture, fresh and nutrient rich media from media inlet port is diverted towards the central axis of the cultivation matrix where the intermingled rotation of the cell carrier discs ensures complete and quick mixing. The unique, efficient and stress-free mixing pattern in DBR technology makes the CellBRx bioreactors the world first truly scalable culture devices from 0.5 L to 200 L of culture volume.

CONFIGURATIONS

The CellBRx bioreactors are available in several formats

- CellBRx 0.5L bioreactors for process development and research work
- CellBRx 5L is pilot scale bioreactors for feasibility studies and pilot scale production
- CellBRx 50L & 200L system for industrial scale manufacturing

CONFIGURATIONS OF CELLBRX BIOREACTORS AT SMALL AND MANUFACTURING SCALE

TECHNICAL SPECIFICATIONS AND CONFIGURATIONS

SCALE VARIANTS

Bioreactors	BRx Volume	Culture Surface Area	Equivalent RB's (850 cm^2 each)	Equivalent CF10 (6320 cm^2 each)
CellBRx 0.5	0.5L	1 m^2, 2.5 m^2	30	4
CellBRx 5	5L	10 m^2, 25 m^2	294	40
CellBRx 50	50L	100 m^2, 250 m^2	2940	396
CellBRx 200	200 L	1000 m^2, 1500 m^2	17647	2373

SYSTEM START-UP REQUIREMENT

	CellBRx 0.5L (8 BRx/system)	CellBRx 5L	CellBRx 50 L	CellBRx 200L
Power Supply	100 - 230 VAC 50-60 Hz	100 - 230 VAC 50-60 Hz	100 - 230 VAC 50-60 Hz	100 - 230 VAC 50-60 Hz
GAS REQUIREMENTS				
O_2	1 Bar	2 Bar	2.5 Bar	2.5 Bar
Co_2	1 Bar	2 Bar	2.5 Bar	2.5 Bar
N_2	1 Bar	2 Bar	2.5 Bar	2.5 Bar
Air	1 Bar	2 Bar	2.5 Bar	2.5 Bar

PROCESS CONTROL SPECIFICATIONS

		CellBRx 0.5 L	CellBRx 5 L	CellBRx 50 L	CellBRx 200 L
pH					
	Measuring Range	6-9 pH with Precision +/- 0.01 pH @ pH 7.0	6-9 pH with Precision +/- 0.01 pH @ pH 7.0	6-9 pH with Precision +/- 0.01 pH @ pH 7.0	6-9 pH with Precision +/- 0.01 pH @ pH 7.0
	Regulation means	CO_2/$NaHCO_3$ Addition	CO_2/$NaHCO_3$ Addition	CO_2/$NaHCO_3$ Addition	CO_2/$NaHCO_3$ Addition
DO					
	Measuring Range	0 to 100 %	0 to 100 %	0 to 100 %	0 to 100 %
	Regulation means	O_2 Addition (GEX Secondary)	AIR/O_2 Addition (GEX Secondary)	Air/O_2 Addition (GEX Secondary)	Air/O_2 Addition (GEX Secondary)
Temperature					
	Measuring Range	25 to 40 °C	25 to 40 °C	25 to 40 °C	25 to 40 °C
	Regulation means	Flexible Silicon Heater	Flexible Silicon Heater	Flexible Silicon Heater	Flexible Silicon Heater
Agitation					
Disc Rotations					
	Range	N A	0 - 50 RPM	0 - 25 RPM	0 - 20 RPM
	Mixing means	N A	Integrated Magnetic Disc Drive	Integrated Magnetic Disc Drive	Integrated Magnetic Disc Drive
Vans Rotations					
	Range	0 - 200 RPM	0 - 100 RPM	0 - 50 RPM	0 - 25 RPM
	Mixing means	Integrated Magnetic Disc Drive	Integrated Magnetic Disc Drive	Integrated Electro-Magnetic Disc Drive	Integrated Electro-Magnetic Disc Drive
Perfusion					
	Regulation	Integrated perfusion means (Self-regulated pumping outflow, Automatic/ manual mode settings)	Integrated perfusion means (Self-regulated pumping outflow, Automatic/ manual mode settings)	Integrated perfusion means (Self-regulated pumping outflow, Automatic/ manual mode settings)	Integrated perfusion means (Self-regulated pumping outflow, Automatic/ manual mode settings)
Gas Flow rates					
	O_2	0 to 0.5 L/min	0 to 1 L/min	0 to 3 L/min	0 to 3 L/min
	CO_2	0 to 0.5 L/min	0 to 1 L/min	0 to 3 L/min	0 to 3 L/min
	Air	0 to 0.5 L/min	0 to 1 L/min	0 to 3 L/min	0 to 3 L/min
	N_2 (optional)	0 to 0.5 L/min	0 to 1 L/min	0 to 3 L/min	0 to 3 L/min
	Data Recording & Trend Visualization	Available on External PC/Laptop	Available on External PC/Laptop	Available on External PC/Laptop	Available on External PC/Laptop
	Alarm Management System	System Integrated (User Specific-optional)	System Integrated (User Specific-optional)	System Integrated (User Specific-optional)	System Integrated (User Specific-optional)
	User specific Customization	Available on External PC/Laptop	Available on External PC/Laptop	Available on External PC/Laptop	Available on External PC/Laptop
	Vessel Type	Only Single Use Culture vessel	Only Single Use Culture vessel	Only Single Use Culture vessel	Only Single Use Culture vessel

SYSTEM SPECIFICATIONS

	CellBRx 0.5L	CellBRx 5L	CellBRx 50L	CellBRx 200L
Dimensional Specifications in mm (H X L X W)				
Controller	518 X 440 X 510	518 X 440 X 510	518 X 440 X 510	518 X 440 X 510
Docking Station	355 X 450 X 432	423 X 550 X 523	397 X 799 X 725	397 X 1049 X 964
Weight				
Controller	35 KG	35 KG	35 KG	35 KG
Docking Station	30 KG	38 KG	46 KG	57 KG
Instrumentation				
pH sensor	1 (Single Use)	1 (Single Use)	2 (Single Use)	2 (Single Use)
Oxygen Sensor	1 (Single Use)	1 (Single Use)	2 (Single Use)	2 (Single Use)
Temperature Probe	1	1	1	1
Biomass Probe	Optional	Optional	Optional	Optional
Pumps	1 - Base addition	1 - Base addition	1 - Base addition	1 - Base addition
	1 - Feed	2 - Media/Feed	3 -Media/Feed/seed	3 -Media/Feed/seed
	1 - Perfusion	1 - Perfusion	1 - Perfusion	1 - Perfusion
	1 - Harvest	1 - Harvest	1 - Harvest	1 - Harvest
	1 - Recirculation	1 - Recirculation	1 - Recirculation	1 - Recirculation
Control System				
System Architecture	PLC- HMI & SCADA			
Compliances	21CFR Part 11 Compliant, GAMP			

Integrated Seed Trail

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