



Deluxe BioRocker

BIOPROCESS CONTROL

PRODUCT SUMMARY

The Deluxe BioRocker provides a closely monitored and highly controlled environment for the growth of viable cells to densities suitable for cell therapy research, process development, and clinical manufacturing operations. We accommodate different cell types and culture conditions by adjusting the rocking platform's motion, speed, and angle.

APPLICATIONS:

The Deluxe BioRocker supports various processes by providing gentle and controlled agitation of the cell culture, efficient mixing, and aeration while minimizing physical stresses on the cells. The Deluxe BioRocker prioritizes cell density and growth rate with a gentle rocking motion to ensure an even temperature, feed addition, gas distribution, and distribution of cells to prevent cell clumping and provide consistent growth rates. The Deluxe BioRocker is ideal for suspension and

adherent cultures, making it a flexible option for a variety of cell culture applications, including:

- Cell Culture & Fermentation
- Cell Therapy
- Gene Therapy
- Biotech Manufacturing

BENEFITS OF THE AES DELUXE BIOROCKER:

- Integrated pumps within the base unit eliminate the need for a separate pump tower, maximizing valuable lab space.
- AES Rocker Bags with built-in optical spot sensor for pH and DO to ensure precise control of the culture environment, enhancing cell growth and viability.
- Advanced monitoring with integrated sensors and remote access allows for real-time data logging and automated control.
- Prevents contamination with a closed system and AES BioRocker Bags.

FUNCTIONALLY CLOSED SYSTEM:

Perform cell expansion in single-use rocker bags with nominal volumes ranging from 10L to 50L. These bioreactors, made from multilayer, laminated, clear USP class VI plastics, provide a functionally closed environment that minimizes the chance of contamination between different patient samples or with adventitious agents.

AUTOMATED PROCESS MONITORING & REMOTE CONTROL:

Users can monitor and control process parameters using their choice of DCS software installed on a local or remote computer. In addition, users can create, edit, and save methods to optimize cell culture protocol. Meanwhile, users can configure alerts for pre-set conditions and report deviations from defined culture parameters.

DESIGNED FOR A REGULATED ENVIRONMENT:

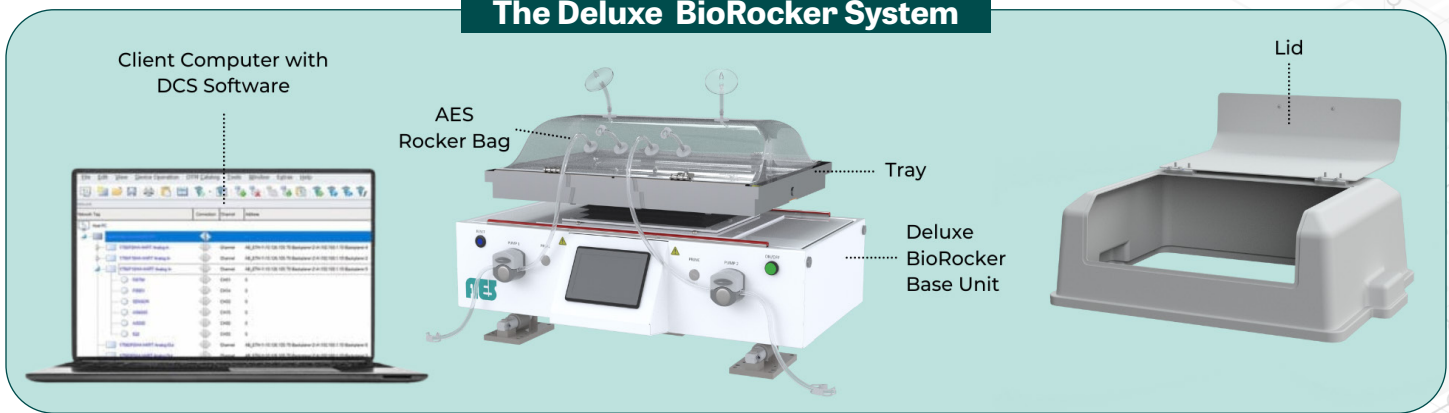
This Deluxe BioRocker is designed to meet the rigorous demands and standards required in a regulated environment. The biorocker is GMP compliant and can be incorporated to meet 21 CFR Part 11 compliance regulations.

and sampling of liquids, the peristaltic pump head ensures gentle handling of shear-sensitive materials. The incorporation of a bi-directional stepper motor not only enhances accuracy but also provides precision in fluid manipulation. Complemented by an efficient controller, this biorocker excels in monitoring and controlling processes within bioprocessing applications. The emphasis on accuracy and gentle handling makes it an ideal choice for those seeking reliable and controlled fluid management.

Temperature Control:

The tray heater efficiently and evenly distributes heat by controlling temperature by integrating sensors in the rocker base. The rocker must be in motion for the heating element to function to reduce the risk of uneven heat distribution in the culture bag. The functionality of the tray heater ensures accurate and stable temperature for variable size and weight applications.

The Deluxe BioRocker System



SYSTEM OVERVIEW

The Deluxe BioRocker System seamlessly integrates its base unit with compatible AES Rocker Bags, providing flexibility for client needs. The client can choose their preferred DCS system for operations management. With an effortless connection to a tray and disposable rocker bag bioreactor, it offers a comprehensive solution. Equipped with mixing, temperature control, gas control, and pH and DO measurement functions, with optional weight measurement, the system ensures efficient and reliable bioprocess control.

BASE UNIT:

The base unit is the main hardware component of the system and provides mixing through rocking reliable temperature measurement from integrated sensors and accurate weight measurement. The bioreactor allows for convenient handling so the user can easily sample and harvest in a tilted position. In addition, the benchtop footprint simplifies placement when space is limited.

Liquid Management:

Two on-board pumps offer a streamlined liquid management system for precise control over flow rates and volumes. Designed to facilitate accurate dispensing

Mixing Rates:

The biorocker offers adjustable parameters for speed, angle, and motion, significantly impacting Rocker Bag bioreactors' mixing. The speed parameter dictates the frequency of rocking cycles per minute, and the angle parameter governs the angle to which the tray will tilt to during agitation.

Gas Control:

The Deluxe BioRocker features advanced gas control functionalities, equipped with three Mass Flow Controllers (MFCs) for CCA, O₂, and CO₂ gases, offering precise regulation of gas flow rates. The operating ranges and flow rate units are configurable, allowing seamless integration with various bioreactor setups. The biorocker ensures accurate and reliable gas transfer, which is vital for maintaining optimal culture conditions.

Measurement of pH & DO:

The Deluxe BioRocker features advanced optical pH and DO sensors with digital transmitters for precise monitoring, ensuring optimal control of the culture environment. The pH sensor delivers stable and accurate measurements, even in harsh conditions, while the DO sensor accurately tracks oxygen concentrations. The Deluxe BioRocker's intuitive software allows users to visualize and analyze the collected data quickly, enabling process optimization.

Weight Measurement (Optional Instrumentation):

The biorocker base unit is equipped with control capabilities to maintain optimal culture conditions. The load cells in the base unit provide precise and continuous weight measurement. Additionally, the adjustable feet of the AES Deluxe BioRocker facilitate equal weight distribution across the load cells.

Trays & Lids:

Trays are available in two sizes accommodating 10L to 20L bags and 20L to 50L bags, respectively. The trays are easily attached to the rocker when in a tilted position. The snap lock mechanism allows users to change and secure rocker bags rapidly. Lids are available for both tray sizes and are used to protect light-sensitive culture medium.

ROCKER BAGS:

Elevate your bioprocessing with AES Rocker Bags, featuring advanced spot sensors for precise monitoring. Available in 20L and 50L volumes, these bags integrate seamlessly into your workflow with convenient disc port connectors. Sterilized via gamma ray radiation and packaged in double-layer PE vacuum bags, they ensure unmatched sterility and purity. The cutting-edge CellBios CSF51 film structure offers excellent clarity and transmittance, while compliance with ISO and USP standards ensures safety and reliability. Ideal for scientists, engineers, and procurement decision-makers, AES Rocker Bags deliver exceptional performance and reliability.

TECHNICAL SPECIFICATIONS

Specifications	Small Tray	Large Tray
Nominal Bag Volume Range	10 L to 20 L	20 L to 50 L
Enclosure Dimensions at 0° Tray Tilt	25" L x 35" W x 16" H 54cm x 69cm x 41cm 21" D x 27" W x 19" H* 54cm x 69cm x 48cm*	27" L x 35" W x 16" H 69cm D x 76cm x 41cm 27" D x 30" W x 19" H* 69cm x 76cm x 48cm*
Rocker Speed	2 to 30 rocks/min < ±1 r/min	
Rocker Angle	2° to 12° ±1.5°	
Tilt Motor Operational Temperature	0° to 85°C	
Tray Heater Operational Temperature	0° to 60°C	
Tray Heater Power Consumption	250 W	
Temperature Element Operating Range	-50°C to 200°C ±0.2°C	
Vent Filter Heater	User Configurable Duty Cycle	
pH Monitoring	(1) Optical pH Sensor	
DO Monitoring	(1) DO Sensor	
On-Board Pumps	(2) Pumps with 24VDC Bi-Directional Stepper Motors	
MFC Quantity & Gas Type	(3) MFC: AIR, O2, CO2	
MFC Instrument Range	0.003 - 50 SLPM (operating ranges and flowrate units are configurable)	
Total Load Cell Capacity*	(3) Load Cells: 150 kg 330 lbs	
Load Cell Safe Load Limit*	200% Emax	
Load Cell Side Load Limit*	100% Emax	
Load Cell Accuracy*	± 1% of readings in net weight working range of 0 to 20 kg	
Cell Culture Bag	AES Rocker Bag, Sartorius**, Cytiva**	

*Optional Instrumentation if configured

** Speak with your Sales Rep to Determine Specific Compatibility

DATA & COMMUNICATION:

The Deluxe BioRocker is an innovative piece of lab equipment that provides precise data and control functions for cell culture applications. The user-friendly interface displays real-time and historical data and can be customized to meet the specific needs of each experiment. Additionally, the platform includes advanced features such as remote monitoring and control, data logging, and alarm notifications, allowing for efficient and reliable operation. Historical data and control parameters can also be stored locally or on removable media and are available via CSV files for viewing in Excel or other enterprise data applications.

HMI (Optional Instrumentation):

Enhance your data interaction and communication capabilities with an HMI (Human-Machine Interface) screen, built into the base unit of the AES Biorocker. This feature seamlessly integrates into the system, offering benefits such as space efficiency, simplified operation, and improved visibility of real-time and historical data. With the HMI screen, users can customize the interface to meet specific experiment needs, ensuring efficient data management and analysis. Moreover, the integrated HMI enhances accessibility and reduces the risk of errors, providing a comprehensive solution for data-driven processes.

Power Supply	U.S.: 110 to 120 VAC, 60 Hz, 6.7 A International: 230 VAC, 50 Hz, 3.4 A
Power Consumption	804 W
Control	
DCS	Rockwell or Preferred DCS System
I/O Interface	Digital IP
Data Logging	Logs 26 process parameters at 1 minute intervals Data is maintained in the event of a power loss. Data can be exported for analysis in other programs. DCS Historian allows for trending data on the device*
HMI Touchscreen*	Resistive
HMI Screen Dimension*	6.5" 16.51cm
HMI Display Type*	TFT Color
HMI Connectivity*	(1) Ethernet Port
HMI Operating System*	Windows CE

*Optional Instrumentation if configured

Rocker Bag Technical Specifications

Production Data	
Bag Volume	20L or 50L
Disc Port Connectors	(1) for 3/8" Tube, (1) for 1/4" Tube, (3) for 1/8" Tube
Sterilization Method	Gamma Ray Radiation (25 - 40 kGy)
Packaging Form	Double-layer PE bag vacuum packaging
Film Material	
Bag Structure	CellBios CSF51: Ultra-Pure PE/EVOH/Ultra-Pure PE(liquid contact layer)
Environmental Requirement	Class 7 Clean Room Environment
Film Thickness	0.325 mm ±0.05
Haze	7%
Clarity	97%
Transmittance	93%
Tensile strength at break	14 MPa
Elongation at break	280%
Elastic Modulus	Below -45°C
Density (g/cm³)	0.9
Water Vapour Transmission Rate (g/M²/24 hrs @ 23°C)	Before Sterilization: 0.35 After Sterilization: 0.32
O₂ Permeability (cm³/M²/24 hrs @ 23°C, 0% RH)	Before Sterilization: <0.05 After Sterilization: <0.05
CO₂ Permeability (cm³/M²/24 hrs @ 23°C, 0% RH)	Before Sterilization: <0.2 After Sterilization: <0.2
Compliance	ISO 10993-4: Hemolysis ISO 10993-5: Cytotoxicity ISO 10993-11/USP <151>: Pyrogen Test ISO 10993-6: Subcutaneous Implantation test ISO 10993-10: Irritation and sensitization tests ISO 10993-11: Acute Systemic Toxicity test ISO 10993-10:2010(E): Sensitization & Irritation USP <85>: Bacterial Endotoxins USP <788>: Particulates USP <1207>: Microbial Immersion Test USP <87>: Biological Reactivity