Automated Engineering Services, Inc.

TECHNICAL BROCHURE

Basic BioRocker

BIOPROCESS CONTROL

PRODUCT SUMMARY

The AES Basic 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 AES Basic 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 AES Basic BioRocker prioritizes cell density and growth rate with a gentle rocking motion to ensure an even distribution of cells throughout– preventing cell clumping and providing consistent growth rates. The AES Basic 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 BASIC BIOROCKER:

- Enhances cell growth by precisely controlling motion and conditions, ensuring even cell distribution.
- Prevents contamination with a closed system and AES BioRocker Bags.
- Advanced monitoring with integrated sensors and remote access allows for real-time data logging and automated control.

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 plastic 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:
We designed the AES Basic BioRocker to meet the rigorous demands and standards required in a regulated environment. The AES BioRocker is GMP compliant and can be incorporated to meet 21 CFR Part 11 compliance regulations.

SYSTEM OVERVIEW

The AES Basic BioRocker System consists of a base unit to be integrated with and rocker bags. The unit can be integrated to the client preferred DCS system allowing the user to manage the system's operations, control, and monitoring from their computer. The base unit connects to a tray and has multiple functions, including heating, culture mixing, and temperature measurement.

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.

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

Mixing Rates:
The AES Basic 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.

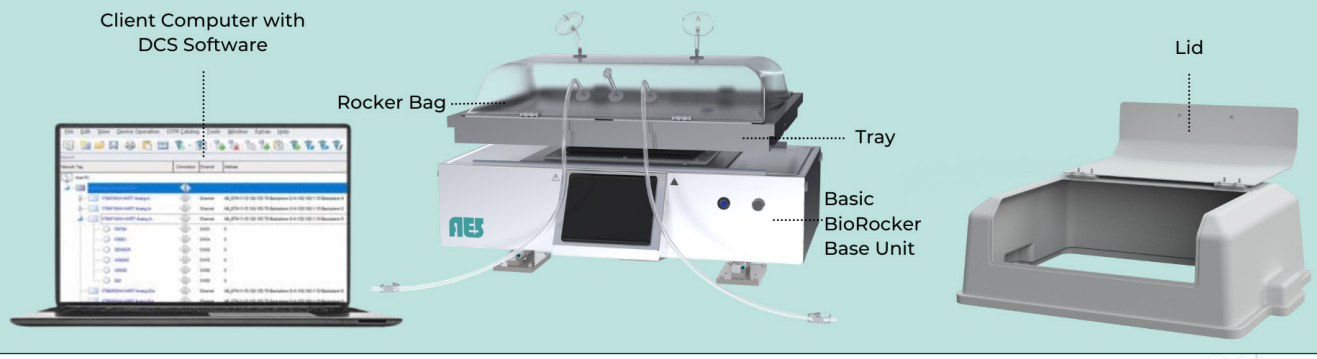
Trays & Lids:
Trays are available in two sizes accommodating 10L to 20L bags and 20L to 50L bags, respectively. The trays are easily attached to the rocker when in a tilted position. The snap lock mechanism allows users to secure bags during installation and when they change rapidly. Lids are available for all tray sizes to protect the culture medium's light-sensitive components and prolong the optical sensors' life.

Weight Measurement (Optional Instrumentation):
The AES Biorocker base unit of the AES BioRocker is equipped with antifoam monitoring and control capabilities to maintain optimal culture conditions. The load cells in the base unit provides precise and continuous weight measurement. Additionally, the adjustable feet of the AES Basic BioRocker facilitates equal weight distribution across the load cells.

AES ROCKER BAGS:
Elevate your bioprocessing with AES Rocker Bags 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.

DATA & COMMUNICATION:
The AES BioRocker is an innovative piece of lab equipment utilizing a 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 can be integrated with advanced features such as remote monitoring and control, data logging, and alarm notifications, allowing for efficient and reliable operation. Historical data and control

The AES Basic BioRocker System



parameters can 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 within the AES BioRocker system.

TECHNICAL SPECIFICATIONS

Specifications	Small Tray	Large Tray
Nominal Bag Volume Range	10 L to 20 L	20 L to 50 L
Weight	45 kg | 99 lbs 50 kg | 110 lbs*	55 kg | 110 lbs 60 kg | 121 lbs*
Enclosure Dimensions at 12° Tray Tilt	21" D x 27" W x 16" H 54cm x 69cm x 41cm 21" D x 27" W x 19" H* 54cm x 69cm x 48cm*	27"D x 30"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	
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, Sartorious**, Cytiva**	
Power Supply	U.S.: 110 to 120 VAC, 60 Hz, 6.7 A International: 230 VAC, 50/60 Hz, 3.4 A	
Power Consumption	804 W	
Control		
DCS	Rockwell or Preferred DCS System	
I/O Interface	Ethernet/IP	
Data Logging	Logs 26 process parameters at 1 minute intervals	
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 Instumentation if configured
** Speak with your Sales Rep to determine specific compatibility

Rocker Bag 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)
Enviromental 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 Steilization:<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