Automated Engineering Services, Inc.

TECHNICAL BROCHURE

Deluxe Benchtop Bioprocess Controller

PRODUCT SUMMARY

The Deluxe Benchtop Bioprocess Controller (BPC) is a versatile stirred-tank bioreactor system perfect for process development, small-scale production, and cell culture applications. It offers precise and predictable monitoring, minimizing the need for repeated runs, thus saving valuable time, effort, and expenses. This controller boasts a design that leverages the same technology platform as the larger bioreactors, ensuring seamless scale-up from benchtop to pilot to full production scale. The bioreactor system is designed to accommodate working volumes ranging from 2L to 15L and is available in various configurations based on your biomanufacturing needs. The Deluxe Benchtop BPC System facilitates the implementation of design of experiment (DoE) strategies in process development, among other applications.

APPLICATIONS:

The Deluxe Benchtop Bioprocess Controller precisely controls agitation and aeration, ensuring optimal growth conditions for your cell culture. This versatile bioprocess controller is ideal for various processes, including suspension, adherent cultures making it a flexible option for a variety of cell culture applications.

- Cell & Gene Therapy
- AAV & Viral Vector Process
- Cell Culture Expansion
- Recombinant Proteins
- Vaccine Production
- Biopharmaceutical Production

BENEFITS OF THE AES DELUXE BENCHTOP BPC:

- Integrates seamlessly and scales from process development to advanced manufacturing, offering versatility for various perfusion applications.

- Maximizes benchtop space and minimizes footprint with it's modular design, making it ideal for labs with limited space while offering robust functionality.
- Optimizes cell culture by precisely controlling agitation, aeration, pH, DO, and temperature, ensuring maximum productivity and efficiency with minimal repeated runs.
- Standard integration with Rockwell™, with deluxe options for DeltaV or your preferred DCS.
- Compatible with various bioreactor vessels, both single- and multi-use, ensuring seamless integration and performance.

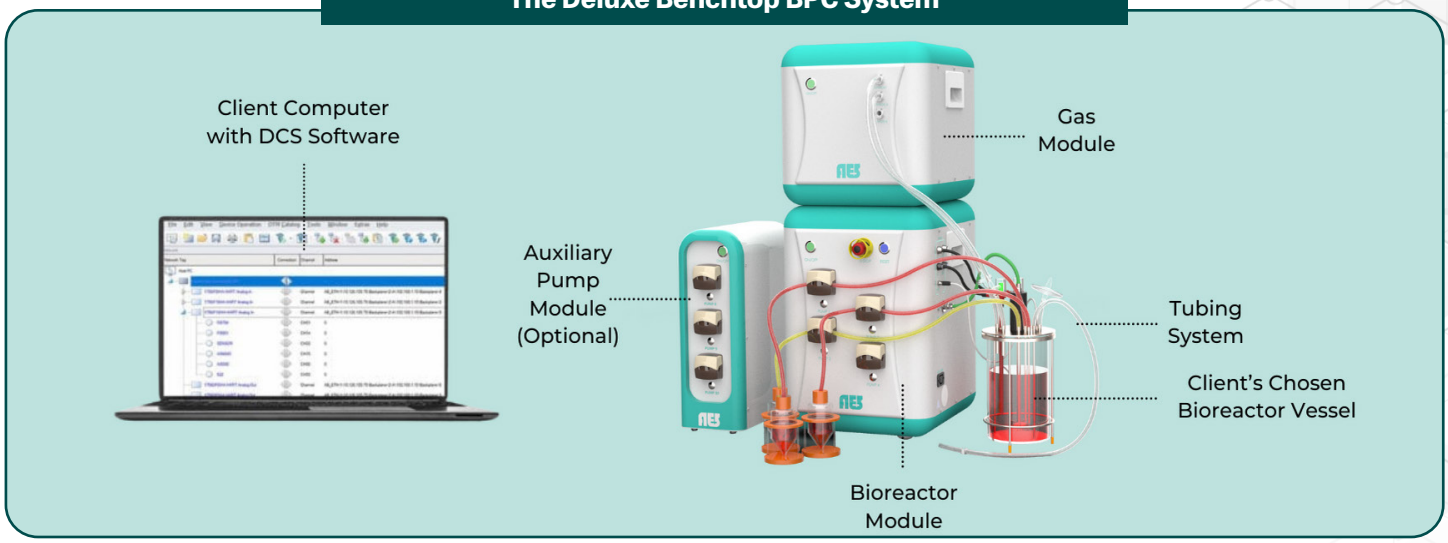
SCALABILITY:
This controller is a versatile and robust piece of equipment designed for process development and integration with advanced manufacturing processes. Its batch, fed-batch, modes offer flexibility for various applications, and its vessel geometry, gas transfer, and mixing are industry-standard. The controller's vessel geometry, gas transfer capabilities, and mixing performance adhere to industry standards. Whether you're involved in technology transfer, process troubleshooting, or development, this controller is the ideal tool to drive innovation and efficiency.

SYSTEM OVERVIEW

Users can customize the Deluxe Benchtop BPC to meet their specific needs due to its flexibility and adaptability. It includes a bioreactor and gas module, with an optional auxiliary pump module for additional functionality. The system is designed to minimize footprint with stackable enclosures, and all components are made of industrial, powder-coated panels to resist corrosion and ensure long-term use. The client can choose their preferred DCS system allowing easy control and monitoring from their computer. In addition, users can customize their cell process culture process to meet specific requirements by setting up manual or semiautomated sequences.

BIOREACTOR MODULE:
The bioreactor module is the system's main component, controlling agitation, liquid management, weight, temperature, pH, and DO with the option of monitoring biomass and CO_2. Due to its high-powered direct and magnetic drive motor assemblies, it can rotate clockwise and counterclockwise and operate four integrated pumps with variable speed modes. This control system monitors real-time data from pH and DO probes.

The Deluxe Benchtop BPC System



AUTOMATED PROCESS MONITORING & REMOTE CONTROL:
Users have the flexibility to configure alerts and set points, tailoring them specifically to their unique application requirements. Monitor trend reports for these process values, gaining valuable insights into the performance of their system. Create, edit, and save methods, enabling them to optimize cell culture protocols according to their needs. This comprehensive suite of features empowers users to effectively manage their operations and identify deviations from the defined culture parameters.

DESIGNED FOR A REGULATED ENVIRONMENT:
This controller can be designed to meet a regulated environment's rigorous demands and standards if required. In addition, this piece of equipment is GMP compliant and can be incorporated to meet 21 CFR Part 11 compliance regulations.

Liquid Management:
The bioreactor module is equipped with four on-board pumps (with an option to add three more pumps via the optional auxiliary pump module). These pumps control liquid flow rates and volumes, enabling accurate dispensing and sampling of liquids. The peristaltic pump head design ensures gentle handling of shear-sensitive materials, while the bi-directional stepper motor provides excellent accuracy and precision. The controller effectively monitors and controls both in bioprocessing applications.

Measurement of pH & DO:
The bioreactor module's pH and DO probes provide real-time monitoring and control of pH and DO levels throughout the bioprocessing application. The pH probe uses industry-proven technology and utilizes an optical DO probe with a stainless steel body. The digital probes work with the controller, enabling real-time monitoring and control of pH and DO. The system's software allows for easy visualization and analysis of the data collected from

the pH and DO probes, providing greater insight into the bioprocessing application.

Temperature Control:
The bioreactor module offers precise temperature control, which is essential for cultivating temperature-sensitive cells or producing heat-sensitive proteins. An optional custom heating jacket is available for the bioreactor vessel, providing even heating for optimal cell growth and chemical reactions. Cooling systems can also be combined with the heating jacket to create a temperature-controlled environment within the vessel.

Weight Measurement (Optional Instrumentation):
Enhance the functionality of your bioreactor module by configuring it with vessel, media feed, and harvest scales. This integration enables the controller to cater to a wide range of applications, including batch, fed-batch cultures. The controller incorporates advanced antifoam monitoring and control capabilities, ensuring optimal culture conditions at every stage of the process. Accurate and continuous weight measurement is achieved through the load cells integrated into the base unit, enabling precise monitoring of antifoam levels. Seamlessly interfacing with your preferred DCS software, the controller automatically delivers the required additions, guaranteeing comprehensive control across all cell culture applications. This streamlined workflow enhances efficiency and productivity.

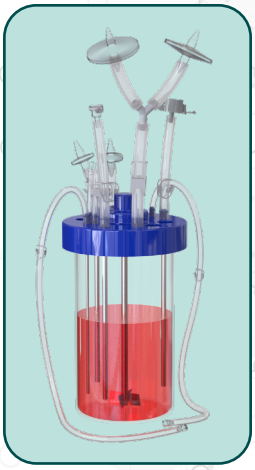
CO_2 Measurement (Optional Instrumentation):
Real-time monitoring and control of CO_2 levels are made possible by the advanced CO_2 measurement capabilities in the controller. This feature ensures optimal conditions for cell growth and chemical reactions throughout your process. What sets this controller apart is its on-board CO_2 measurement capabilities, which eliminate the need for external equipment, streamlining the setup process and enhancing user-friendliness.

Biomass Measurement (Optional Instrumentation):
For those seeking advanced monitoring capabilities, the bioreactor module offers an optional biomass measurement feature. This functionality includes a capacitance probe input, allowing real-time monitoring and control of crucial parameters like the glucose feed rate. With a proven track record in optimizing cell culture, vaccine, and viral vector production processes, this cutting-edge instrumentation provides comprehensive, real-time insights into live cell density and viable biovolume profiles. By harnessing PAT principles, our biomass measurement solution enhances process monitoring, automation, and control. This indispensable tool for biopharmaceutical manufacturing improves productivity and efficiency in continuous production processes.

GAS MODULE:
The gas module offers efficient communication through Ethernet/IP protocol, enabling seamless connectivity between the system, mass flow controllers (MFC), and other devices. It comes with four MFCs that allow precise control of Clean Compressed Air (CCA), O_2, CO_2, and N_2 flow rates. Gas flow to Bioreactor HEADSPACE, SPARGE A, or SPARGE B is managed through a triple output manifold, with each MFC having independent shutoff valves. The system can accommodate up to six MFCs, facilitating the integration of additional gases for diverse overlay and sparging strategies. By leveraging MFCs and agitation, the gas module ensures reliable and accurate bioprocess control, guaranteeing superior outcomes.

FLUID HANDLING:
Explore our seamlessly integrated solutions for fluid management, encompassing both our meticulously designed single-use tubing system and a range of vessel options tailored to your processes.

Vessel Selection:
Select from our array of vessel options tailored to your processes. Choose the convenience of single-use consumables, eliminating the need for cleaning and sterilization, or opt for the durability of autoclavable vessels suitable for long-term use or specific experimental conditions. Regardless of your choice, our commitment to supporting your needs with consumables and expertise remains steadfast. Please ensure your vessel is compatible to optimize your processes effectively. Together, our integrated solutions create a seamless workflow, ensuring precision and efficiency in your laboratory endeavors.



AES Tubing Set:
Optimize your bioprocessing operations with our versatile Tubing Sets, engineered for seamless integration with our Deluxe BPC. These tubing sets are designed to be compatible with your chosen vessel, ensuring that no matter your specific requirements, we have the right solution for you. Crafted from premium materials, these tubing sets deliver consistent and reliable performance in bioprocessing applications. Assembled and packaged in a controlled cleanroom environment, they meet the highest standards of sterility and quality.
With advanced sterilization methods ensuring safety and biocompatibility, our Tubing Sets are the ideal solution for maintaining the integrity of your bioprocessing workflows.

AUTOMATION & CONTROL SYSTEMS:
The Deluxe Benchtop BPC's automation and control options offers flexible integration into your setup, supporting DCS or 'stand alone' control as well as Industrial Ethernet communication standards.. The standard offering for the controller is DeltaV, providing real-time data acquisition and enabling accurate process control. Convenient trend analysis further enhances the capabilities of this controller. With streamlined tech transfer, scale-up, and recipe sharing, this controller simplifies research and facilitates seamless automation across different stages of the product development process.

DATA & COMMUNICATION:
The Deluxe Benchtop BPC offers robust data and communication capabilities for precise control and insightful analysis. Its user-friendly interface displays real-time and historical data, which can be customized to suit your specific needs. This controller ensures efficient and

reliable operation with remote monitoring, data logging, and alarm notifications. This controller can seamlessly integrate with external systems and tools for enhanced process analysis. Choose from local/removable media storage options to easily access historical data and control parameters.

AES Historian Database (Optional):
The optional DCS layer includes an AES Historian, a comprehensive database for historical storage, retrieval, and integration into your bioprocess control system. The AES Historian offers the following features:

- Fully integrated history configuration & data collection status collection for every value
- Fully functioning historian on each DCS workstation
- Scalable plant historian for all BPS units in the system
- Integrated tools for viewing historical data, including Excel-based reporting and analysis
- Open connectivity for integration with third-party Historians
- Historical data accessible in operator displays

TECHNICAL SPECIFICATIONS

Bioreactor Module	
Enclosure Specifications	
Benchtop Footprint (H x W x D)	25” x 15” x 20”
Power Requirements	120-230 VAC, 50/60 Hz, 1200 Watts
Vessel Compatibility	Eppendorf**, Sartorius**, Applikon**
Agitation	
Agitation Direction Control	Bi-Directional
Motor Speed (Maximum Range)	600 RPM – Mammalian Cell Culture Applications 1200 RPM – Microbial Fermentation Applications
Liquid Control	
On-Board Pumps	(4) pumps with Bi-Directional Stepper Motors
Pump Head Type	Peristaltic, Flip-Top Pump Heads
Pump Speed Range	0.2 - 200 RPM
Tubing Compatibility	AES Tubing Set or L/S -13, -14, -16, - 25, -17, -18
Process Analytics	
Temperature	0 – 100 ^{o}C ± 0.15 ^{o}C
pH	2 – 12 pH
DO	0 – 100% Air Saturation ± 1% reading
Biomass Permittivity*	0 – 100 pF/cm ± 2-3% reading
CO_2 Gas Saturation*	0 – 50% ± 10% reading
Weight Measurement*	
Vessel Scale Capacity	60 Kg, ± 0.001 kg readability, 0.03% FS error
Vessel Scale Communications	Digital Ethernet/IP
External Equipment and Instrumentation Specifications*	
Weight Measurement	
Vessel Scale Communications	Digital or Analog*
Platform Scales	3 kg ± 0.05 g, 6 kg ± 0.1 g or 60 kg ± 0.1 kg
Platform Scale Communications	Digital Modbus RS232 communication
Hanging Load Cells	3 kg ± 0.05 g readability
Heating Applications*	
Heating Jacket	Custom Designed Based on Vessel Size
Heating Jacket Power	Controlled Power from Bioreactor Module (600 W) using an IEC C13 plug and cable adapter

*Optional Instumentation if configured
** Speak with your Sales Rep to Determine Specific Compatibility

Auxillary I/O	
External Turk BLCDN I/O Module	4 x Analog Input Channels
Configuration Types per Input Channel	0 – 10 VDC, 0 – 20 mA, or 4 – 20 mA
Gas Module	
Enclosure Specifications	
Benchtop Footprint (H x W x D)	15” x 15” x 18”
Power Requirements	120-230 VAC, 50/60 Hz, 550 Watts
Mass Flow Controller Specifications	
Standard Model	
MFC Quantity & Gas Type	(3) to (6) MFCs: CCA (clean compressed air), O_2, CO_2, N_2*, AIR*, O_2*
Instrument Range	0.003 – 50 SLPM (operating ranges and flowrate units are user-configurable)
Communication Protocol	Digital – RS485 communication
High-Performance Model*	
MFC Quantity & Gas Type	(3) to (6) MFCs: CCA (clean compressed air), O_2, CO_2, N_2*, AIR*, O_2*
Instrument Range	0.003 – 50 SLPM (operating ranges and flowrate units are user-configurable)
Communication Protocol	Digital – Ethernet/IP communication
Auxiliary Pump Module*	
Enclosure Specifications	
Benchtop Footprint (H x W x D)	19” x 7” x 15”
Power Requirements	120-230 VAC, 50/60 Hz, 1440 Watts
Liquid Control	
On Board Pumps	(3) Pumps
Pump Head Types	Peristaltic, Flip-Top Pump Heads
Pump Speed Range	0.2 - 200 RPM
Tubing Compatibility	L/S -13, -14, -16, - 25, -17, -18
Automation & Control Software	
Standard Offering	Rockwell™
Deluxe Offering	AES Library DeltaV™, Process Sequence Model functionality DeltaV™ based Perfusion control
Optional Features	DeltaV™ configuration of auxiliary I/O signals or custom ancillary equipment/instrumentation

*Optional Instumentation if configured

TUBING SPECIFICATIONS

Production Specifications	
Tubing Materials	Platinum-cured Silicone, Thermoplastic Elastomer
Adapter Materials	Polypropylene
Pinch Clamp Materials	Polypropylene
Sanitary Materials	Gasket: Polycarbonate Clamp: Nylon End Cap: Polypropylene
Environmental Requirement	ISO 14644-1 Class 7 Cleanroom Environment
Shelf Life	2 Years from the Date of Manufacture
Sterilization Method	Gamma Irradiation
Compliance/Biocompatibility	USP Class VI and ISO 10993 Standards