

Laboratory / Pilot / Production Scale Fermenter

Unique & high durable system for research and Production Suitable for both microbial and cell culture application Operational flexibility for Batch, Fed batch, continuous /Perfusion culture Compliance all cGMP, ASME & BPE Std





Salient Features

• Durable & Reliable

Designed for both research and production.

• Superior Construction

Flat top lid with no welded ports.

• Regulatory Compliance

Meets cGMP, ASME, and BPE standards.

• Versatile Applications

Suitable for microbial and cell culture processes.

• Operational Flexibility

Supports batch, fed batch, continuous, and perfusion cultures.

• Regulatory Compliance

Zero dead leg block valves in all transfer/feed lines.

• Efficient Design

Automatic process transfer/feed with SIP/CIP integration.

• Specialized Cell Culture Features

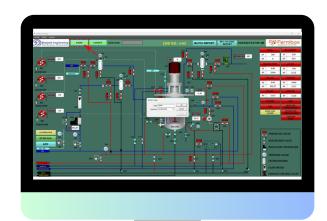
Rotor filter for perfusion and bubble-free gassing for shear-sensitive cells.

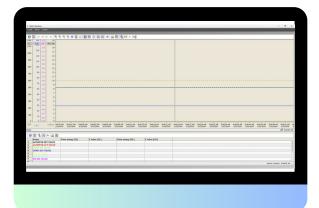
• Enhanced Stirring

Special stirrer systems for high oxygen requirements and high-density cultures.

• Efficient doshing

Mechanical feeder without valve operations for seamless nutrient delivery.





Biojenik Engineering SCADA Software

Biojenik Engineering's SCADA software is designed for real-time monitoring and control, offering a range of features to improve efficiency and ensure compliance.

- Software: Siemens WinCC.
- Simulation and Auto-Tuning: Generates random process values for simulation and auto-tuning.
- Third-Party Integration: Free OPC server for third-party device integration.
- Remote Operation: Webex-based remote operation/control of setpoints.
- Customized Interface: Personalize display to show Process, Profiles, Set Points, and Cascade.
- Batch Management: Manage batches and track them using tags.
- Access Control: Different access levels for enhanced security.
- **Dosage Tracking:** Monitor and record material consumption during production.
- Real-Time Data Recording: Automatic recording and trending of setpoints and measurement values.
- Data Export: Export data to Excel for analysis and reporting.
- Data Comparison: Compare and analyze data for improved decision-making.
- Event Alarms & History: Alerts for issues, historical data access, and ANSI-18.2 compliant alarm management.
- Audit Trail: Record-keeping compliant with 21 CFR Part 11 standards.
- **Lifetime Support:** One-time license with lifelong updates and support.

Benefits:

- Simplifies process monitoring and control.
- Increases efficiency by automating tasks and tracking.
- Ensures compliance with regulatory standards.
- Provides actionable insights with data comparison and analysis.



Technical Specification

SPECIFICATIONS	LABORATORY SCALE FERMENTER	PILOT SCALE FERMENTER	PRODUCTION SCALE FERMENTER
Vessel	Small, compact vessel for lab experiments	Larger than laboratory scale, for process optimization	Industrial-sized for large-volume production
Total Volume	1L to 50L	50L to 500L	500L to 20000L and beyond
Materials	SS 316L for product contact, SS 304L for non-contact parts	SS 316L for product contact, SS 304L for non-contact parts	SS 316L for product contact, SS 304L for non-contact parts
Surface Finish	≥ 0.4µ with mirror finish electro-polished (interior) ≥ 0.2µ with matte finish (Exterior)	≥ 0.4µ with mirror finish electro-polished (interior) ≥ 0.2µ with matte finish (Exterior)	≥ 0.4µ with mirror finish electro-polished (interior) ≥ 0.2µ with matte finish (Exterior)
Top/Bottom Driven	Top-driven agitator	Top-driven agitator	Top-driven agitator
Sealing Mechanisms	Single or double mechanical seals	Single or double mechanical seals	Single or double mechanical seals
Cooling Arrangement	Steam or glycerin cooling system	Steam condensate or glycerin cooling systems	Steam condensate or glycerin cooling systems
Safety Interlocks	Basic safety mechanisms	Enhanced safety interlocks for large-scale processes	Advanced safety interlocks integrated into process control
Magnetic Coupling	Available for top-driven agitators	Available for top-driven agitators	Available for top-driven agitators
Stirrer Types	Rushton, propeller, pitched-blade, BT6 ,Marine, etc	Rushton, propeller, pitched-blade, BT6 ,Marine, etc	Rushton, propeller, pitched-blade, BT6 ,Marine, etc
Sampling System	SIP - Sterile Sampling system / Sterile Sampling Collection Unit (On Request)	SIP - Sterile Sampling system / Sterile Sampling Collection Unit (On Request)	SIP - Sterile Sampling system / Sterile Sampling Collection Unit (On Request)
Multiple Gas Mixing Station	Two Gas (Air + O2), Four Gas Mixing (Air, N2, O2, CO2) Other Gases (On request)	Two Gas (Air + O2), Four Gas Mixing (Air, N2, O2, CO2) Other Gases (On request)	Two Gas (Air + O2), Four Gas Mixing (Air, N2, O2, CO2) Other Gases (On request)
Sparger Options	Standard ring sparger or micro sparger	Multiple sparger options (standard ring, micro sparger, sinter)	High-efficiency sparger systems with customizable pore sizes

Sterile Filters	Available in single or double filters (Code 7)	Available in single or double filters (Code 7)	Available in single or double filters (Code 7)
Exhaust Line	exhaust line with condenser, Exhaust heater (On request)	exhaust line with condenser, Exhaust heater (On request)	exhaust line with condenser, Exhaust heater
Heating Options	Electrical /Steam heating available	Electrical and steam heating options available	Steam heating
Closed Loop Jacket Heating	Available in single or double PHE	Uses single or double PHE for efficient heat transfer	Uses single or double PHE for efficient heat transfer
Sterilization	FSIP / ESIP	FSIP / ESIP	FSIP / ESIP
Automation	Fully automated or semi-automated	Fully automated or semi-automated	Fully automated with high-level control integration
Sampling	Manual or automated SIP sampling with sterile containers	Auto or manual SIP sampling with sterile containers	Auto or manual SIP sampling with sterile containers
Harvest Arrangement	Manual or automated flush bottom harvest system	Manual or automated flush bottom harvest system	Manual or automated flush bottom harvest system
Human Interface	HMI / PC with SCADA interface	HMI / PC with SCADA interface	HMI / PC with SCADA interface
Customization	Basic recipe customization options	Supports customizable recipes and advanced features	Full customization for complex recipes and real-time adjustments
pH/Redox, DO, CO2, OD	Sensors with single or retractable housing	Sensors with single or retractable housing	Sensors with single or retractable housing
Level/Volume	Measured with piezoresistive/Delta P / Load Cell technology	Measured with piezoresistive/Delta P / Load Cell technology	Measured with piezoresistive/Delta P / Load Cell (Upto 2000 L) technology
Antifoam	Conductive type with height-adjustable probe	Conductive or pneumatic type with adjustable probe	Advanced foam control with real-time monitoring and adjustment
Jenik SCADA	Process monitoring & Control, Complete data Management	Process monitoring & Control, Complete data Management	Process monitoring & Control, Complete data Management
Feed System	Peristaltic pump with variable speed control / Sterile cross Value for auto feed	Peristaltic pump with variable speed control / Sterile cross Value for auto feed	Peristaltic pump with variable speed control / Sterile cros Value for auto feed

Accessories	Sterile housing, cross valve assembly, flexible hygiene pipes	Auto-sterile housing, valve assembly, flexible transfer pipes	Fully automated sterile transfer, housing, and valve systems
Advanced Features	Complete automated / Data management / remote monitoring / Audit trails for cGMP Validation	Complete automated / Data management / remote monitoring / Audit trails for cGMP Validation	Complete automated / Data management / remote monitoring / Audit trails for cGMP Validation
QC Documentation	The system complies with all QA/QC requirements, including IQ, OQ, and DQ compliance, validated for GMP practices.	The system complies with all QA/QC requirements, including IQ, OQ, and DQ compliance, validated for GMP practices.	The system complies with all QA/QC requirements, including IQ, OQ, and DQ compliance, validated for GMP practices.
Compliance Standard	 ASME - BPE 2022 for vessel and piping manufacturing ASME Section VIII (Division 1) for pressure vessel. US FDA 21 CFR 177.2600 for gaskets and O-rings EN/IEC-60204 and UL 508 for electrical work IEC 60529 Standards EU GMP Guide Annex 11 for computerized systems US FDA 21 CFR Part 11 for automation 	 ASME - BPE 2022 for vessel and piping manufacturing ASME Section VIII (Division 1) for pressure vessel. US FDA 21 CFR 177.2600 for gaskets and O-rings EN/IEC-60204 and UL 508 for electrical work IEC 60529 Standards EU GMP Guide Annex 11 for computerized systems US FDA 21 CFR Part 11 for automation 	 ASME - BPE 2022 for vessel and piping manufacturing ASME Section VIII (Division 1) for pressure vessel. US FDA 21 CFR 177.2600 for gaskets and O-rings EN/IEC-60204 and UL 508 for electrical work IEC 60529 Standards EU GMP Guide Annex 11 for computerized systems US FDA 21 CFR Part 11 for automation









Our Valuable Clients

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Biojenik Engineering Services

We offer a comprehensive range of services to ensure the smooth operation and longevity of your systems:









SCADA

Training



Customized Engineering Solutions



Technical Support & Troubleshooting



Warranty

Services

AMC &

CMC Services Relocation & Retrofitting Services



Rapid 24x7 Replacement Customer **Parts Delivery** Support

Our Certifications











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