

# AbioSUS

## Single-Use Bioreactor



# AbioSUS Single-Use Bioreactor

The AbioSUS Single-Use Bioreactor is a comprehensive system comprising a stainless-steel bag holder (integrated with a TCU for temperature control), the AbioControl IDS.S controller, and the AbioBag culture bag.

Designed to replicate the conditions of traditional stirred-tank bioreactors, the AbioSUS ensures that process conditions are comparable, enabling seamless transition between research, development, and production platforms.

Available in standard sizes of 50L, 200L, 500L, 1000L, and 2000L, with customization options, the AbioSUS supports a wide range of upstream cell culture applications for antibodies, vaccines, and cell/gene therapies.



	AbioSUS 50L	AbioSUS 200L	AbioSUS 500L	AbioSUS 1000L	AbioSUS 2000L
Overall dimensions (WxDxH, mm)	800x1215x1930	818x1340x2029	1144x1326x2450	1387x2037x2868	1392x2320x3768
Weight (kg)	250	420	735	1200	2278
Working volume (L)	12.5-50	50-200	125-500	250-1000	500-2000
Bag diameter (mm)	370	585	815	991	1295
Bag height (mm)	666	1055	1467	1800	2330
Working volume filling height (mm)	480	783	1005	1360	1670
Working volume ratio of height to diameter	1.30	1.34	1.23	1.36	1.29
Impeller diameter (mm)	143	225	310	379	492
Maximum stirring speed (rpm)	240	200	160	140	95

## Stainless-Steel Bag Holder

### Dual-Jacket Design:

- Both the bag holder and door feature a dual-jacketed structure connected to an integrated TCU, facilitating temperature control via water circulation within the jacket.
- Temperature Range: 8°C - 40°C  $\pm 0.1^\circ\text{C}$  (requires cooling water  $\leq 8^\circ\text{C}$ ).

### AbioBag® Culture Bag:

- The culture bag is mounted on a fixed frame and, once connected to the AbioSUS, forms a complete bioreactor system.
- Constructed from 7-layer coextruded film.
- Includes a dual-blade Marine impeller and dual bottom sparger ports.

### Weighing Sensor Support Bracket:

- During transport or long periods of non-use, the bracket absorbs load to prevent sensor damage.
- During operation, the bracket is removed, allowing the C6-grade weighing system to monitor the culture weight directly.

### Fixed Support Frame:

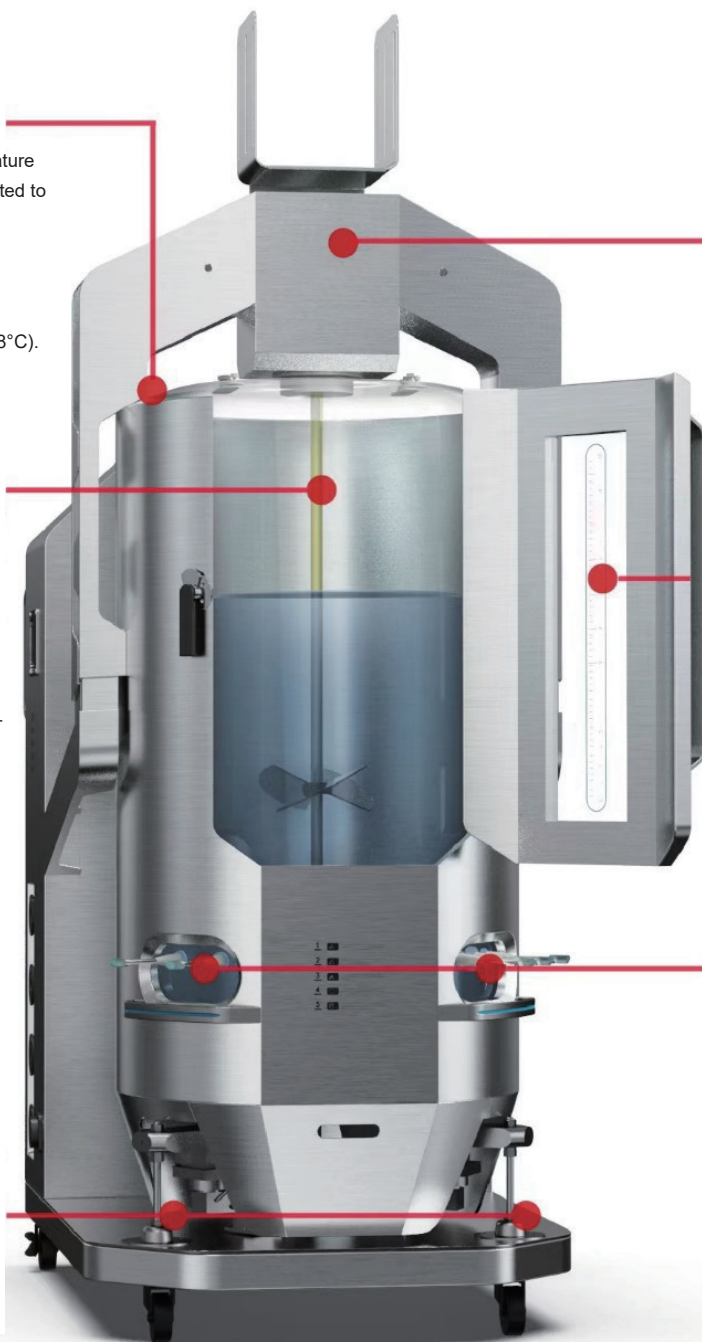
- Secures the AbioBag culture bag, accommodates various filters, and organizes cables and tubing for enhanced durability and appearance.
- Exhaust gas electric heating blanket.
- -Servo-driven stirring motor.

### Door with Observation Window:

- Large single-opening door simplifies bag replacement and features a transparent, graduated window for easy observation of the bag's contents
- Dual-jacketed designed door for better temperature control

### Sensor Operation Area:

- Mirrors the sensor interface arrangement of traditional stainless-steel bioreactors for familiar operation, ensuring full immersion of sensors in the culture medium while minimizing damage risk from proximity to the impeller.
- Supports traditional and single-use pH/DO sensors, with options for dual pH and dual DO configurations.



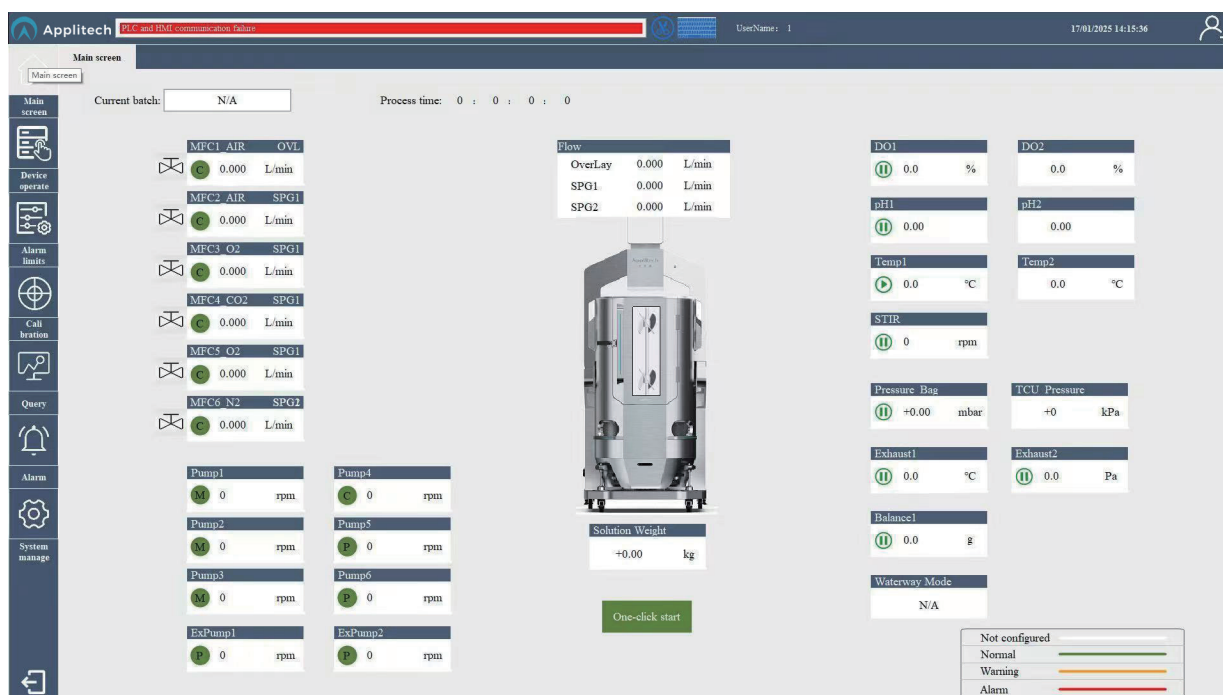


## AbioControl IDS.S Controller

- The controller's modular design offers flexible configurations suitable for a wide range of applications, supporting single-use bioreactors from 50L to 2000L.
- Includes five levels of operational access (View, Operator, Engineer, Supervisor, Administrator). Permissions management ensures controlled production processes, with audit trail capabilities logging all operations.
- Equipped with an anti-mistouch and screen-lock function to secure the production process.
- Supports multiple control loops, including temperature, agitation, pH, and DO. All process parameters are displayed, and process control strategies can be adjusted as needed.
- Flexible Cascade Control Loops allows switching based on control requirements to maintain parameter stability, ensuring experimental reproducibility and process consistency.
- Supports integration with third-party devices such as variable-speed pumps, mass flow controllers (MFCs), balances, and off-gas analyzers via 4-20mA or Modbus. It facilitates interaction with multiple control software systems and seamless data transfer.
- Customizable configurations to meet client-specific requirements
- Equipped with a 24V DC UPS power supply to ensure the stability of the control and monitoring system and maintain continuous data recording.
- Enables quick switching of bottom aeration pathways via software.
- Designed to minimize footprint, saving valuable space.



### ► Operation Interface

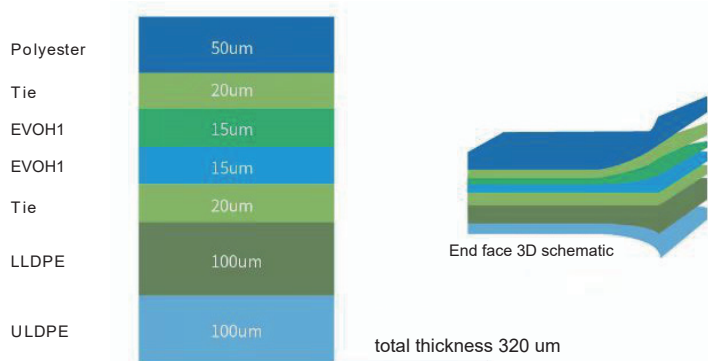


## AbioBag Culture Bag

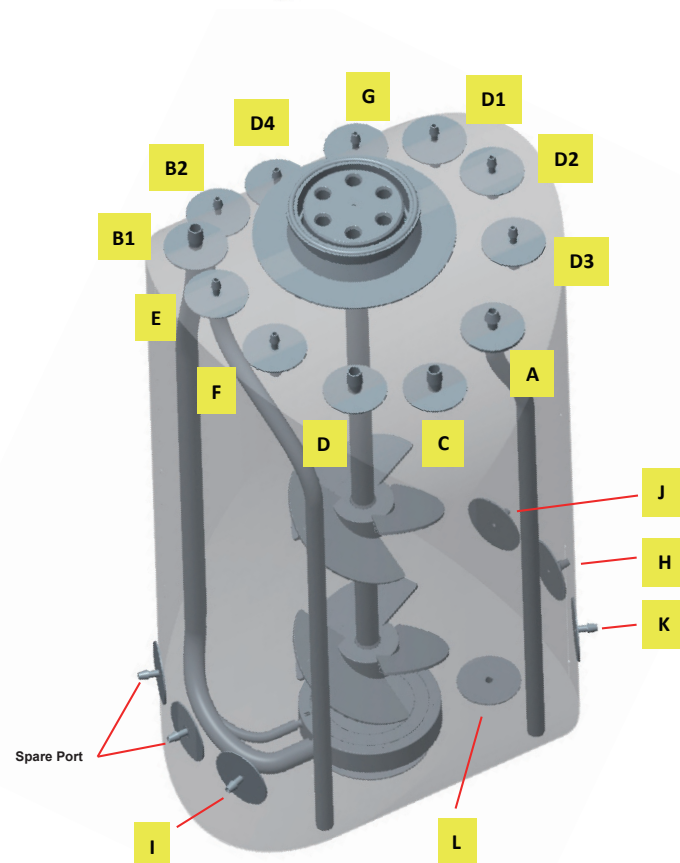
AbioBag culture bags are constructed using a 7-layer composite co-extruded film, free from animal-derived components, with a total thickness of 320  $\mu\text{m}$ , providing excellent strength and resistance to mechanical stress.

The innermost layer is made of ultra-low-density polyethylene (ULDPE), which directly contacts the sample, providing superior biocompatibility and the necessary flexibility for various applications.

These bags are sterile, pyrogen-free, and highly gas-tight, meeting international biosafety standards such as USP Class VI and ISO 10993 with complete material certification and can be extensively customized to meet specific customer requirements.



Port Location	Port ID	Port Type
Top	A	Medium Inlet
Top	B1	Bottom Aeration (Macro-Bubble)
Top	B2	Bottom Aeration (Macro-Bubble)
Top	C	Exhaust Outlet
Top	D	Top Vent
Top	D1	Auxiliary Feed 1
Top	D2	Auxiliary Feed2
Top	D3	Auxiliary Feed3
Top	D4	Defoaming
Top	E	Inoculation
Top	F	Alkali Supplement
Top	G	Air Pressure Monitoring
Left window	I	Sample
Left window	NA	Spare port x 2
Right window	H	pH
Right window	J	Temperature Monitoring
Right window	K	DO
Bottom	L	Harvest



## AbioSUS Single-Use Bioreactor Features

- ▶ Top-mounted motor drive facilitates quick and convenient assembly and disassembly.



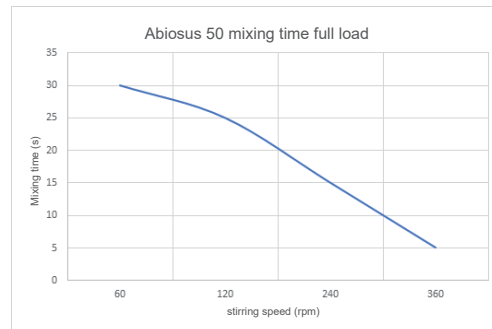
- ▶ Large single-door design allows for easy loading and unloading of the culture bag.



- ▶ Double-Layered Jacket for the entire bag holder (including the door).  
Water circulation system for heating or cooling, with synchronized temperature control on the door to enhance overall temperature uniformity.



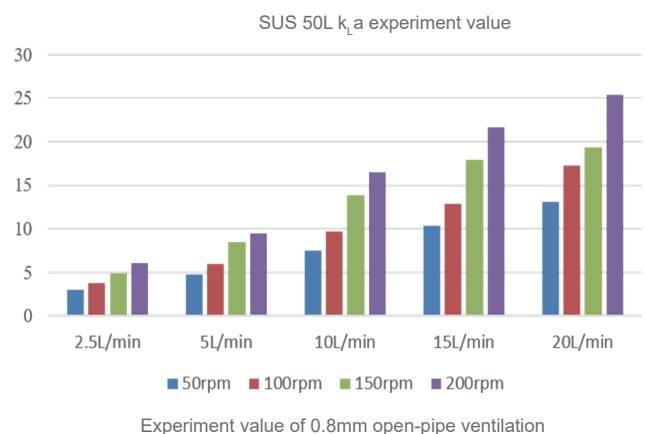
- ▶ Dual impeller design ensures consistent and efficient mixing across different volumes.



AbioBag 50L Mixing Time Measurement:  
Mixing Time 60rpm < 30s, 120rpm < 25s,  
240rpm < 15s, 360rpm < 5s

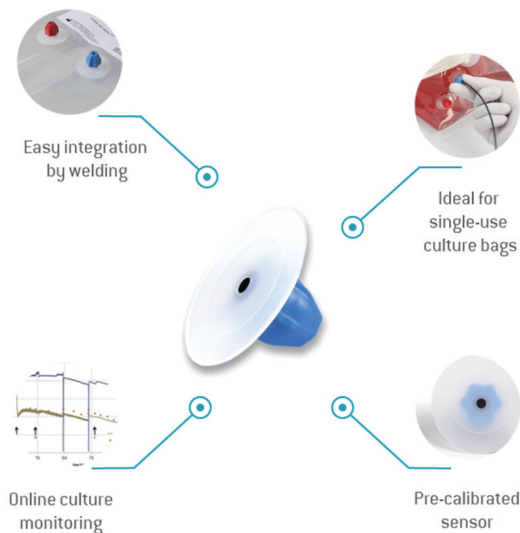


- ▶ Features a 0.8 mm macro-bubble and a 150  $\mu$ m micro-bubble aeration system, allowing for online switching between multiple aeration strategies. Improves  $K_La$ , enhances pH control, and reduces foam formation. Aeration port types and specifications are customizable.



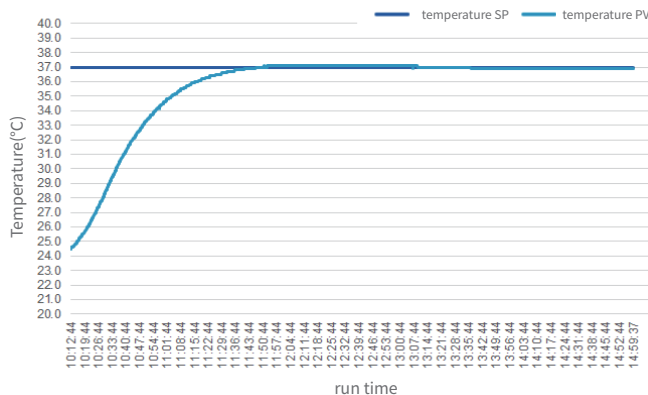


- Supports both traditional and single-use pH/DO sensors, with the ability to simultaneously use dual pH and dual DO sensors.



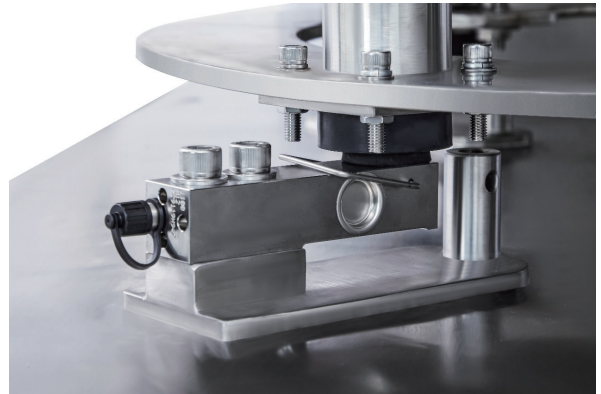
- The bag holder integrates the TCU Temperature Control System eliminating the need for external heating or cooling devices (Includes TEC cooling to prevent overheating). The TCU is controlled through the IDS.S controller.

AbioSUS 50 Heating time (28~37°C)

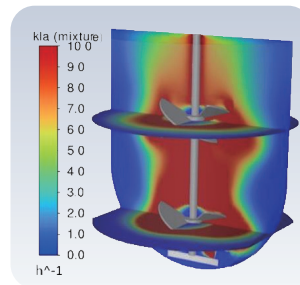


Heating up stabilization time 70min, fluctuate 37°C±1°C

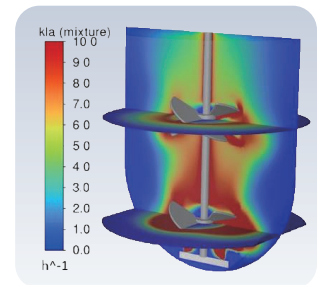
- C6-Grade load sensors provides highly accurate weight measurements.



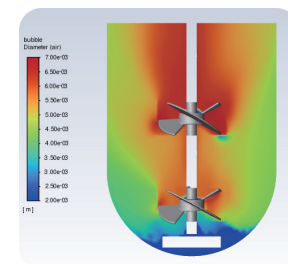
- Performance verification of the single-use bioreactor was conducted using CFD (Computational Fluid Dynamics) analysis. The results demonstrated excellent oxygen transfer capabilities and effective mixing uniformity. The bioreactor provides low shear force and consistent heating, meeting the condition requirements for optimal cell culture growth.



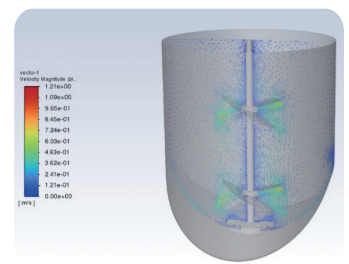
KLa (rpm 1)



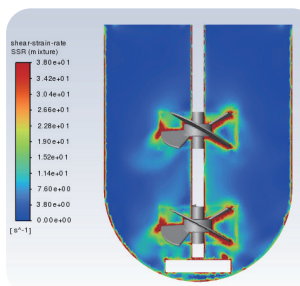
KLa (rpm 2)



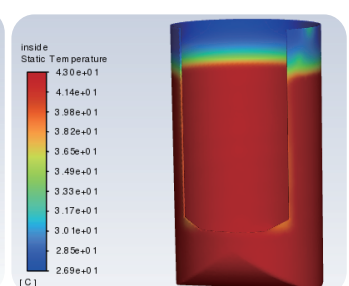
Bubble diameter distribution



Mixing effect



Shear force distribution



Tank wall temperature

# AppliSoftec Bioprocess Information Management System

AppliSoftec is available in two series: AbioPIMS and AbioExpert, with each series divided into four versions based on functionality: Lite, Standard, Advanced, and GMP.

AbioPIMS series supports AbioSUS Single-Use Bioreactors, AbioWave Single-Use Rocking Bioreactors, and AbioBundle M/E/P Series Glass Bioreactors.

AbioExpert Series supports AbioBundle M/E/P Series Bioreactors, AbioPilot Stainless Steel Bioreactors, and can also collect data from analytical devices such as Nova and Kaiser.

The AppliSoftec Series Software is also compatible with the Applikon my-Control, ez-Control, and ez2-Control series bioreactors.

The AbioBundle M/E/P Series Bioreactors come with AbioPIMS Lite or AbioExpert Lite Software by default, with optional upgrades to higher-level versions within the same series.

## AbioPIMS Bioprocess Information Management System

AbioPIMS (Process Information Management System) is a process information system developed by Applitech for the industrial biotechnology and biopharmaceutical industries.

- **Features:**

- Enables enterprise-wide data management and information sharing across all divisions and subsidiaries.
- Rapidly addresses the needs of bioprocess development and production.
- Enhances efficiency, cost-effectiveness, and reduces engineering expenses.
- Compatible with major bioreactor platforms, integrating seamlessly with analytical and operational instruments for comprehensive data acquisition.

- **Access Management:**

Password protection; customizable access/operation permissions; user group configuration.

- **21 CFR Part 11:**

Adheres to 21 CFR Part 11 standards, offering three security levels: Operator, Supervisor, and Administrator.

Provides event logging, audit trails, and electronic signature capabilities.

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- **Configuration:**

With a variety of data acquisition port configuration, the system specifies the data acquisition channel and data import template file.

- ① Supports multi-device integration with connection to parameter configurations and control strategies.

EDIT DEVICE

GENERAL SETTING

CONNECTION SETTING

STORAGE SETTING

Polling Rate (ms)

1000

Maximum Retry Times

1

Reconnection Speed (s)

10

IP

192.168.1.100

Port

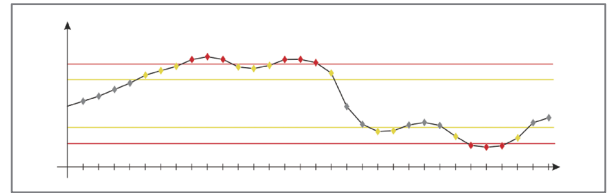
1883

Device Ident...

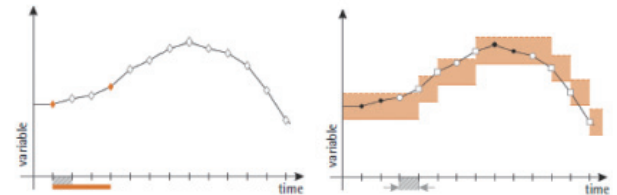
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Connection Detection

- ② Advanced alarm settings: high-high, high, low, low-low thresholds with customizable alarm and response strategies.



- ③Flexible storage modes: periodic or event-based, with value transformations and display configurations.

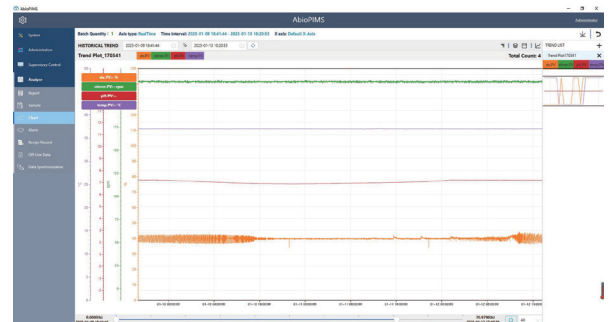


- OPC:

Built on an OPC platform, the OPC Client ensures flexible device connectivity, enhancing control over critical process parameters.

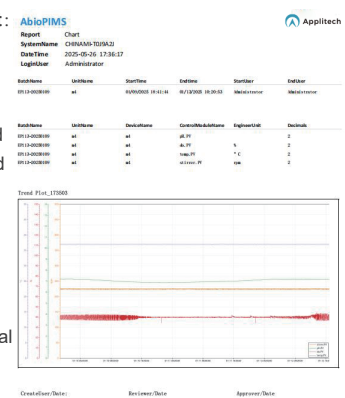
- UI:

Intuitive configuration processes streamline usability and accelerate task execution. Navigation tools allow quick access to configuration, monitoring, trending, alarms, and sampling modules.



- **Data Monitoring & Management:**

Comprehensive monitoring and historical data recording with periodic and event-driven save modes; ensures data integrity and security, enabling fast, robust, and searchable data management; supports exporting data and configuration information into customizable reports; includes extensive system logs, alarm histories, and traceable operational records.



■ **CHART:**

The chart window provides robust visualization capabilities, allowing users to view all relevant process parameters and configure online trends as needed:

- ① Options for zooming, panning, stretching, clipping, and selecting time ranges. Users are also able to modify curve styles, choose to hide or display parameters, and add, edit, or delete individual charts.
- ② Compares and track process data across up to 8 historical batches simultaneously, aligned on a process timeline; synchronizes comparisons between current running data and historical data on the same timeline for comprehensive analysis.



## AbioExpert Bioprocess Information Management System

AbioExpert is a professional software solution independently developed by Applitech, specifically designed for stainless steel bioreactor applications and built in parallel with AbioPIMS. It is widely applicable in industrial biotechnology and biopharmaceutical industries.

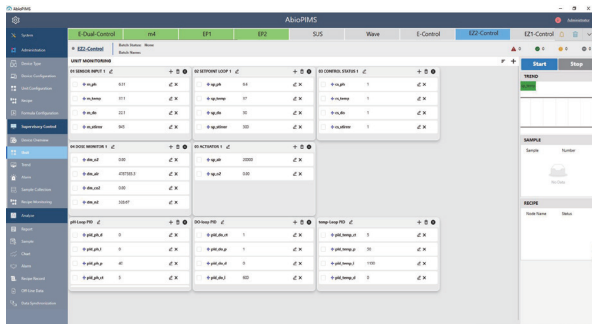
While AbioExpert shares core functionalities with AbioPIMS, its application range differs. The AbioExpert series is primarily intended for AbioPilot Stainless Steel Bioreactors and does not support AbioSUS Single-Use bioreactors or AbioWave Rocking Bioreactors.



### MONITOR:

Quick switching to 24 monitoring units, allowing detailed visualization of all relevant information.

Customizable monitoring module displays and navigation to menus like batch operations, alarms, recipes, real-time trends, and sampling.



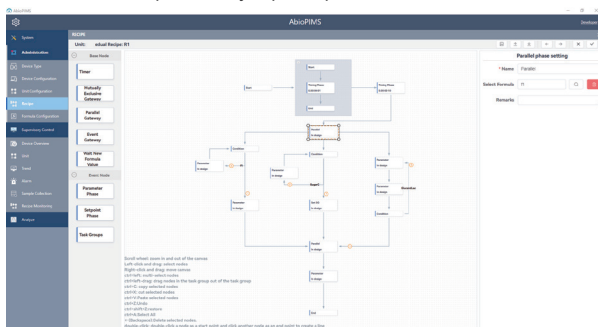
**CONTROL:** Capability for individual or batch parameter control.

### Recipe Design:

Simple and intuitive recipe design guided by on-screen instructions.

Allows advanced control strategy development, automatically adjusting setpoints based on time and cultivation conditions.

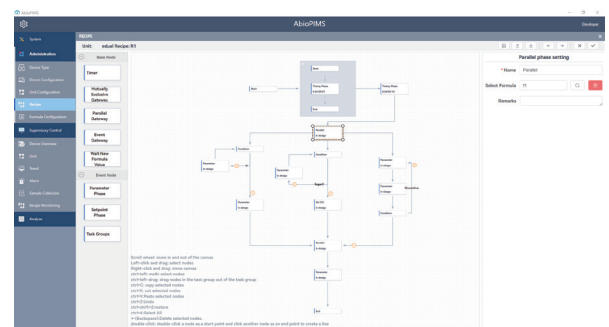
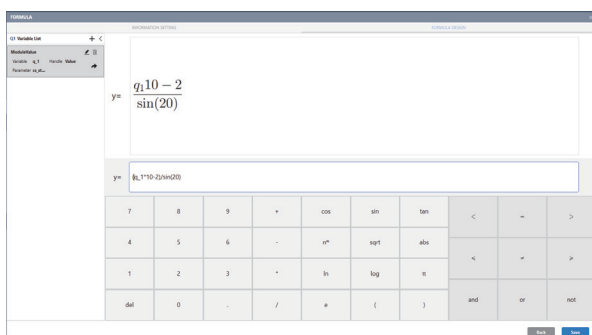
Requires no programming skills; users can drag and drop logic blocks to create branches, loops, waits, jumps, or parallel executions.



### Calculator Module:

Efficiently transforms data with calculation tools for key bioprocess parameters and indirect variables.

Integrates seamlessly into recipe modules to enable logical connections and process automation.



## Additional Information

### Free Trial

All AppliSoftec software series come with a free trial for the first 60 days post-installation.

### Software Updates

AppliSoftec software is continuously updated, and customers can freely upgrade to the corresponding versions.

### Minimum System Requirements

Processor/Clock Rate: Multi-core processor, 2.5 GHz

RAM: 8 GB (16 GB recommended)

Hard Disk Space: 256 GB

Optical Drive: DVD-ROM drive

Network Adapter: 1+ LAN adapter, RJ-45, 100 Mbit

Graphics Card: DirectX 10, 1 GB RAM (recommended)

Screen Resolution: 1920 x 1080, 100% scaling

Display Monitor: 23.8-inch monitor

Operating System: Microsoft Windows 10 (64-bit)

Runtime Components: .NET Framework 4.0 / .NET Framework 5.0 / .NET Core 3.1

Other Software: Microsoft Excel (2013 or newer recommended) / SQL Server 2014 / MongoDB

## AbioPIMS Series Software Feature List

AbioPIMS Specifications	AbioPIMS Lite	AbioPIMS Standard	AbioPIMS Advanced	AbioPIMS GMP
<b>GENERAL</b>				
User interface languages	Chinese, English			
Operating system	Windows 10 64-bit			
Communication drivers included	IDS.W, IDS.S, m-Control, e-Control,ePlus-Control, eDual-Contorl, p-Control; my-Control, ez-Control, ez2-Control			
Number of supported process units	24	24	24	24
Measurement of process values from controllers	Yes	Yes	Yes	Yes
Control of process setpoints in process controllers	No	Yes	Yes	Yes
Starting and stopping of control loops	No	Yes	Yes	Yes
Programming of local process controllers	No	No	Yes	Yes
Reading of calibration data	No	No	Yes	Yes
Automatic report generation	No	Yes	Yes	Yes
21 CFR part 11 compliant	No	optional	optional	Yes
GAMP5 compliant	Yes	Yes	Yes	Yes
ISA S88 standard	Yes	Yes	Yes	Yes
Password protection	No	Yes	Yes	Yes
User definable access rights	No	Yes	Yes	Yes
Remote Access	No	optional	Yes	Yes
Process value alarms	Yes	Yes	Yes	Yes
Process value simulation	Yes	Yes	Yes	Yes
OPC UA/DA client	Yes	Yes	Yes	Yes
Auto start after power failure	Yes	Yes	Yes	Yes
<b>DATA MANAGEMENT</b>				
Database management	Microsoft SQL/MongoDB			
Minimum sampling frequency	1 s	1 s	1 s	1 s
Sample frequency selectable per parameter	Yes	Yes	Yes	Yes
On line data collection	Yes	Yes	Yes	Yes
Off line data collection	Yes	Yes	Yes	Yes
Data export to Excel	Yes	Yes	Yes	Yes
Data export in ASCII format	Yes	Yes	Yes	Yes
Graph export in graphics format	Yes	Yes	Yes	Yes
On-line calculations using on-line and off-line data	No	Yes	Yes	Yes
Configuration management	No	Yes	Yes	Yes
Sample data management	No	Yes	Yes	Yes
<b>DATA DISPLAY</b>				
Line graphs	Yes	Yes	Yes	Yes
Maximum Number of y-axes per Graph	6	6	6	6
Procedure flow chart	No	Yes	Yes	Yes
Combination of current and historic data in graphs	Yes	Yes	Yes	Yes
Combination of different active batches in graphs	Yes	Yes	Yes	Yes
Measured data table display	Yes	Yes	Yes	Yes
Scatter plots	Yes	Yes	Yes	Yes
Storage of predefined graph settings	Yes	Yes	Yes	Yes
<b>SUPERVISORY CONTROL</b>				
Programming of time based actions	No	No	Yes	Yes
Programming of event based actions	No	No	Yes	Yes
Manual setting of local control setpoints	No	Yes	Yes	Yes
Recipe definition	No	No	Yes	Yes
<b>OTHER</b>				
Event viewer for system comments	Yes	Yes	Yes	Yes
Audit trail	No	optional	optional	Yes
Validation support	No	optional	optional	Yes
Service & support package	1 <sup>st</sup> year			

## AbioSUS Single-Use Bioreactor Technical Specifications

Parameters	AbioSUS 50L	AbioSUS 200L	AbioSUS 500L	AbioSUS 1000L	AbioSUS 2000L
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Working Volume Filling Height (mm)	480	783	1005	1360	1670
Working Volume H/D Ratio	1.3	1.34	1.23	1.36	1.29
Impeller Diameter (mm)	143	225	310	379	492
Maximum Stirring Speed (rpm)	240	200	160	140	95
Exterior Surface	304 stainless steel, brushed				
Sensor Port	Two sensor viewport interfaces located on the lower left and right sides.				
Temperature Control	Integrated TCU with a vessel/door double-jacket water circulation system for heating or cooling (requires connection to a cooling water source).				
Agitation	Top servo motor drive				
Temperature Range	8-40°C (cold water below 8°C is required)				
Water Inlet Pressure	0.2MPa	0.2MPa	0.2MPa	0.2MPa	0.2MPa
Drainage Compressed Air Pressure	0.2MPa	0.2MPa	0.2MPa	0.2MPa	0.2MPa
Heating Power	2000W	3000W	5000W	7500W	7500W
Chilled Water Connector	One inlet and one outlet, both equipped with quick-connect fittings with a sanitary clamp specification of 50.5mm/DN25.				
Power Requirement	220V/16A/50Hz	220V/16A/50Hz	220V/16A/50Hz	220V/16A/50Hz	220V/16A/50Hz
Integrated Sensors	Temperature Sensor	Temperature Sensor	Temperature Sensor	Temperature Sensor	Temperature Sensor
Weighing Function	3-point weighing system, C6 grade	3-point weighing system, C6 grade	3-point weighing system, C6 grade	3-point weighing system, C6 grade	3-point weighing system, C6 grade
Exhaust Heating Blanket	Up to 2	Up to 2	Up to 2	Up to 2	Up to 2

## AbioControl IDS.S Controller Technical Specifications

Parameters	AbioControl IDS.S	Parameters	AbioControl IDS.S
Aeration Module	Total 3 ports: Top port x 1: Air, CO <sub>2</sub> (optional) Bottom port x 2: Air, O <sub>2</sub> , CO <sub>2</sub> , N <sub>2</sub> (optional)	Temperature sensor	JUMO PT100 x 1(up to 2)
		Temperature measuring range	0~100°C
MFC	Up to 6, minimum switching ratio is 1.5%FS	Pressure detection	China, 0~6kpa
Rotameter	Optional, accuracy ±5%FS	Exterior Surface	304 stainless steel, brushed
Aeration Switching	The software can switch the bottom sparger mode of Air and O <sub>2</sub>	Overall dimensions (WxDxH, mm)	700x874x1958
Peristaltic Pump	Up to 6 pumps: 2 fixed-speed pumps are standard, up to 4; 2 variable-speed pumps are standard, up to 4.	Footprint	0.63m <sup>2</sup>
Supports pH1	Presens, fluorescent single-use electrodes	Weight	220kg
pH1 Measuring Range	5.5~8.5	Installation Method	Movable pulley platform
Supports pH2	Hamilton, electrochemical single-use electrodes	Screen size	18.5 in.
pH2 Measuring Range	3~10	User level permission	Three user level login permissions
Supports pH3	Mettler, traditional electrochemical electrodes, reusable	Log recording	Compliant with FDA 21 CFR Part 11 standards.
pH3 Measuring Range	0~12	Hardware system	SIMATIC S7
Supports DO1	Presens, fluorescent single-use electrodes	SCADA system	HTE/winCC NetSCADA configuration software
DO1 Measuring Range	0~100%SAT	Uninterruptible Power Supply (UPS)	24V UPS to maintain 10min computer operation
Supports DO2	Hamilton, fluorescent single-use electrodes	Power requirement	220V/10A/50Hz
DO2 Measuring Range	0~300%SAT	Gas supply requirement	Air/O <sub>2</sub> /CO <sub>2</sub> /N <sub>2</sub> (optional) 0.2~0.4Mpa(2~4bar)
Supports DO3	Mettler, traditional Clark polarographic electrodes, reusable	Operating ambient temperature	18~26°C
DO3 Measuring Range	0~300%SAT	Operating humidity requirement	40~60%RH






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