



**DiSTEK**

**Bione 1250** BIOPROCESS CONTROL STATION

# THE NEW interFACE of BIOREACTORS!

Distek, Inc. has earned a place on the modern bioprocessing laboratory benchtop with the release of the BIONe 1250 Single and Dual Bioprocess Control Stations.

Modular, flexible, and highly customizable, the BIONe 1250 systems are ready to support the nuanced requirements of your specific Upstream Bioprocesses.

BIONe 1250 Controllers are compatible with both autoclavable and single-use vessels. The systems are also capable of supporting both cell culture and fermentation processes.

Standard controller options such as OPC and Additional Input & Outputs expand the capabilities of the controller. Such features provide end users with nearly limitless process expansion potential for whatever future bioprocesses they desire to engineer.

## BIONe 1250

### FEATURES, ADVANTAGES & BENEFITS

- Customizable Single or Dual Controller Configurations
- Modern Touch Screen Interface
- Variable Speed, Bidirectional Pumps
  - 4 Pumps on Single Controller
  - 8 Pumps on Dual Controller
- Low Friction Magnetic-Drive Agitation
- Suitable for Cell Culture & Microbial Upstream Bioprocesses
- Compatible with Autoclavable and Single-Use Vessels
- Extensive Data Trending Capabilities
- Preloaded Process Recipes and Cascade Loops
- Support for Additional Inputs & Outputs
  - Analog and Digital Auxiliary Components
- OPC Compliance (UA or DA)
  - Email and Text Message Process Alerts



# CUSTOMIZABLE BIOPROCESSING CONTROL

LEFT SIDE, RIGHT SIDE  
or DUAL SETUP

ROTAMETERS or  
AUTO FLOW CONTROL

UP TO 5 GAS  
CONTROL MODULES



SINGLE-USE or  
AUTOCLAVABLE VESSELS



**SINGLE-USE**



**CELL CULTURE**



**MICROBIAL**

# HIGHLIGHTED FEATURES

## DO & pH CAPABILITY

- Optical or Analog pH
- Optical or Analog DO
- Optional Integrated Single-Use pH Probe

## GAS CONTROL

- Up to 5 Gas Control Modules

## CULTURE VESSELS

- Single-Use Cell Culture (2L / 5L)
- Autoclavable Cell Culture (2L / 5L / 10L)
- Autoclavable Microbial (2L / 5L / 10L)

## PUMP CONFIGURATION

- Left Side, Right Side or Dual

COMPACT BIOPROCESS  
BENCHTOP EFFICIENCY



DUAL CONFIGURATION  
HIGHLIGHTED FEATURES

#### COMPACT FOOTPRINT

- Powerful bioprocessing control now comes in a compact 18" (W) x 22" (H) x 27" (D) footprint with the release of the BIONE 1250 Dual Bioprocess Controller

#### INCREASED PRODUCTIVITY

- Double your process throughput with simultaneous control of two independent bioreactor or fermentation systems from a single central tower

#### FAMILIAR USER INTERFACE

- Same intuitive touchscreen and advanced bioprocessing options as found on the BIONE 1250 Single Bioprocess Controller systems

# CONVERT TO A **SINGLE-USE** **BIOREACTOR** IN SECONDS!

Distek, Inc. has developed a benchtop scale single-use bioreactor (SUB) for mammalian cell growth, cell therapy, insect cells, and other unique applications performed in a stirred tank bioreactor. The gamma irradiated BIONe SUB is engineered with a disposable headplate welded to a triple-layered liner that can be easily inserted into a non-sterile bioreactor glass vessel, converting it to a disposable SUB within a matter of seconds. Upon media addition, the liner expands and molds to the glass vessel, preserving the geometry of the existing bioreactor. The BIONe SUB's liner material emulates the large-scale SUBs used in pilot and commercial biopharm production facilities around the world. Performing R & D studies using the most similar material on the market streamlines your tech transfer and can de-risk your process BEFORE transferring to pilot scale.



## BIONe

SINGLE-USE HEADPLATE

CUSTOMIZABLE  
ABOVE & BELOW  
THE HEADPLATE

- 2L & 5L Working Volume
- Optional Single-Use pH Probe
- Increased Throughput
- Weldable Tubing
- Flute, Micro & Open Pipe Sparging Options
- Non-Invasive DO & Optional pH Probe Ports
- USP Class VI Materials
- Repligen® ATF Perfusion Tube Compatible
- Animal Derivative-Free
- Low Antioxidant Liner Material
- Compatible with Most Manufacturers' Glass Vessels and Controllers

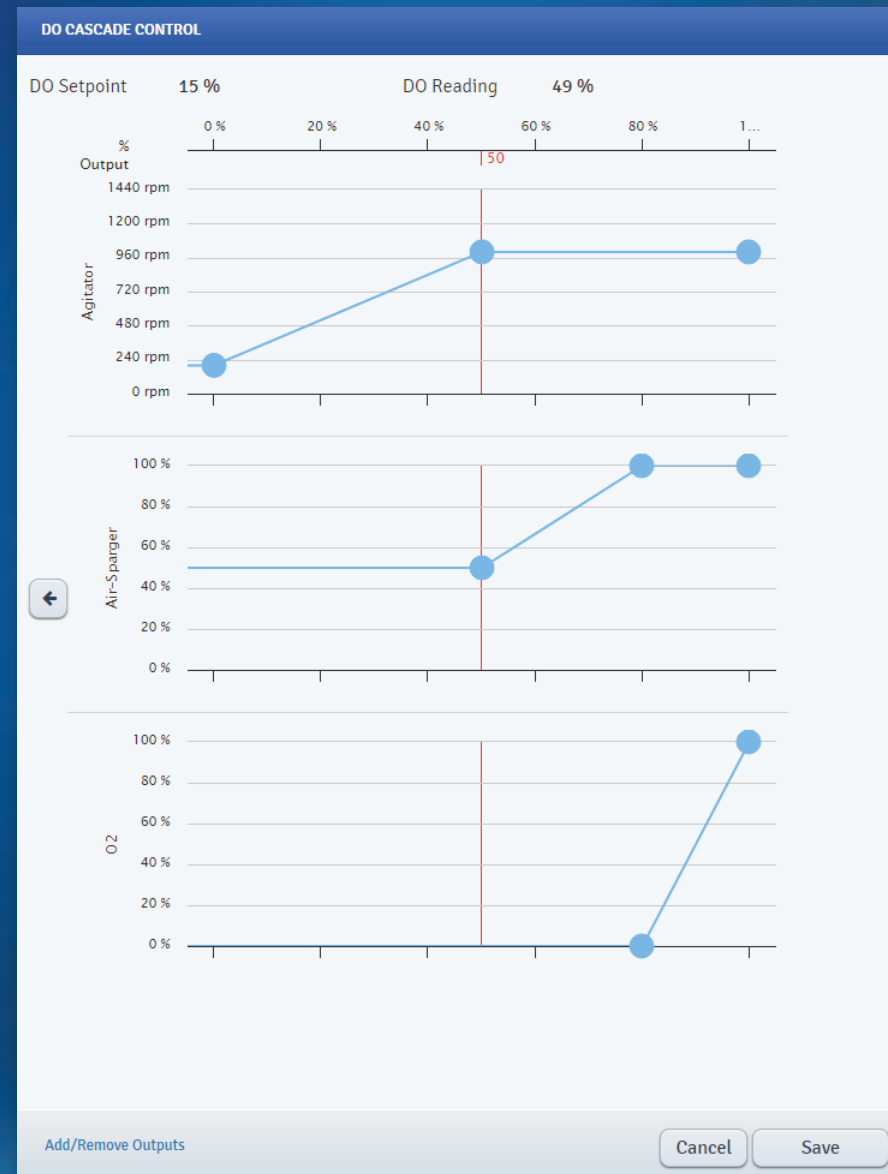
SINGLE-USE LINER

GLASS VESSEL



## PRELOADED & ADAPTIVE PROCESS CONTROL

- Preloaded process recipes support decreased developmental timelines, allowing your team to get your bio-processes up and running faster
- All pre-programmed recipes include PID and cascade definitions that can be customized by end users for optimal process control
- Cascade loop visualization provides end users a valuable tool for intuitive control loop tuning and overall process optimization



## DATA TRENDING REDEFINED

### PROCESS TREND DATA

- Up to eight process trends can be clearly and effectively visualized on screen for real-time process analysis
- Controller stores up to 30 days of process data, with timepoints every 30 seconds
- Process Trend Data are easily exportable as .csv files

### REAL-TIME RUN COMPARISON

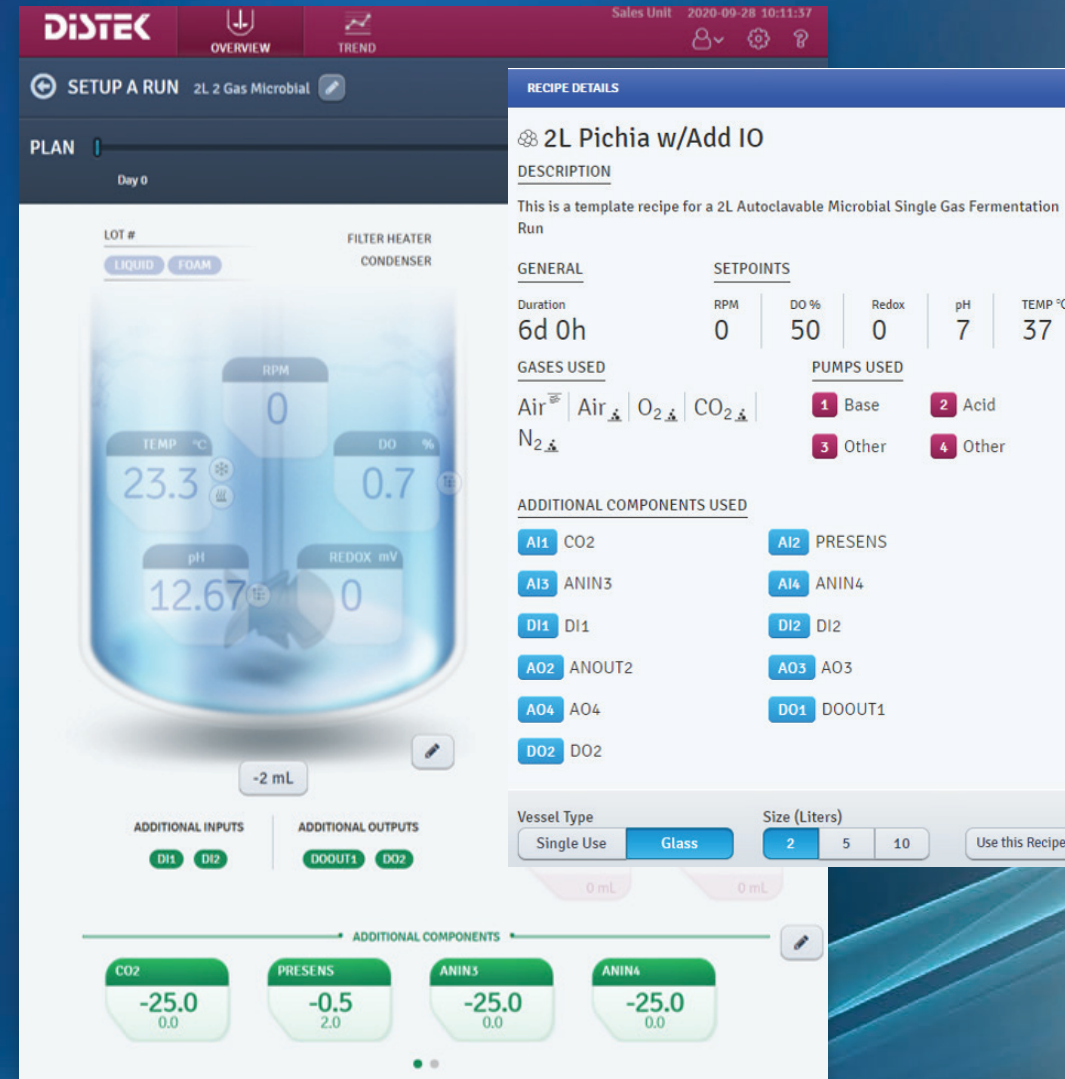
- Compare Feature allows for current online data to be compared to previous runs in real-time

### REAL-TIME EVENT NOTES

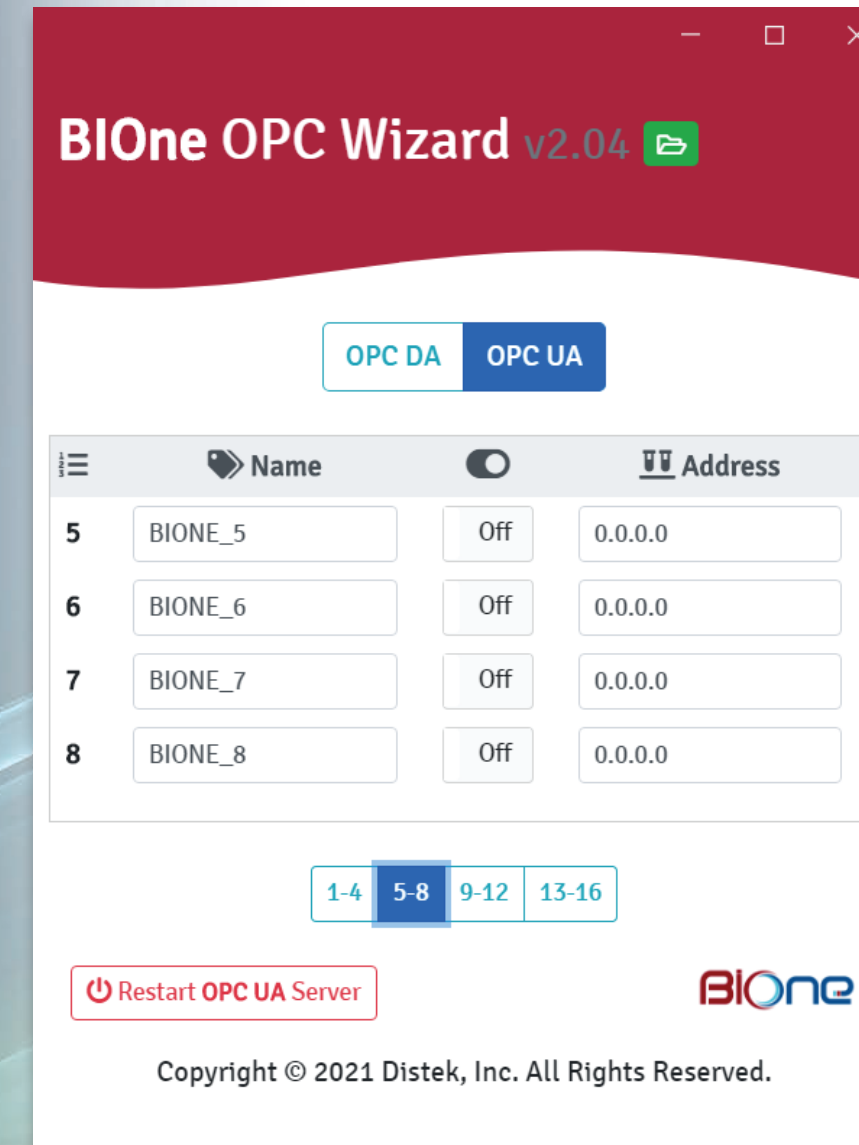
- Events Feature allows for real-time process documentation of specific time points

## EXTENSIVE ADDITIONAL COMPONENT INTEGRATION

- The BIONe 1250 Bioprocess controller systems can support integration to the majority of the auxiliary bioprocessing monitoring tools available on the market
- The Additional I/O Module supports the integration of up to 12 components to a single BIONe 1250 system
  - 4 Analog Inputs
  - 4 Analog Outputs
  - 2 Digital Inputs
  - 2 Digital Outputs
- Data from all integrated additional devices can be programmed to drive cascade loops within the BIONe 1250 system, further enhancing your process control



## OPC COMPLIANCE SUPPORTS cGMP APPLICATIONS



### UA & DA OPC COMPLIANT

- The BIONe 1250 systems offer both UA and DA OPC compliance to support connectivity to the SCADA software of your choice

### cGMP DATA TRACKING

- OPC Compliance supports cGMP data tracking and audit trail functionality for the BIONe 1250 when combined with your team's choice of a suitable SCADA system
- This capability makes the BIONe 1250 a viable candidate for supporting GLP studies or even small-scale GMP manufacturing

### AUTOMATION POTENTIAL

- SCADA integration can support the automation of complex bioprocesses, saving laboratory time and resources

### REAL TIME PROCESS ALERTS

- Email and text notifications for alerts and alarms

## CUSTOMIZABLE ONLINE PROCESS ANALYTICS

- Configure your BOne 1250 Bioprocessing Controller with a custom array of online process analytics
- Real-time, trendable, online process data helps maximize the value of each experimental iteration
- Customize the online analytics for your bioprocess by choosing from a wide selection of optional Process Analytical Technologies (PATs):
  - Electrochemical pH
  - Optical pH
  - Polarographic Dissolved Oxygen
  - Optical Dissolved Oxygen
  - Dissolved Carbon Dioxide<sup>1</sup>
  - Glucose Concentration<sup>1</sup>
  - Optical Density / Biomass<sup>1</sup>

<sup>1</sup>Integration of these analytics requires **Additional Input / Output** option for BOne 1250 Controller



- Remove unreliable stir bars & stir plates from your upstream & downstream benchtop bioprocesses
- Record & Save finalized process recipes to standardize your small volume mixing and purification processes
- Magnetic drive agitation & direct temperature control support the creation of robust Scale Down Models (SDMs)
- Trendable & Exportable Data can be easily analyzed and uploaded to Electronic Laboratory Notebooks (ELNs)
- Gamma-Irradiated BOne Single-Use Mixing Vessels are assembled in an ISO-certified cleanroom helping to reduce product pool endotoxin levels

## SMALL VOLUME MIXING SOLUTION FOR UPSTREAM & DOWNSTREAM APPLICATIONS

### APPLICATIONS

- Buffer Preparation
- Filtrate Collection
- Final Fill & Formulation
- Material Hold Validation
- Media Preparation
- Product Pool Adjustment







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Distek, Inc. is a leading manufacturer of laboratory testing instruments for the pharmaceutical and biotechnology industry for over 45 years, as well as an experienced provider of validation and qualification services. Distek engineers highly innovative, technically modern and user-friendly instruments that provide many innovative features to customers, worldwide. These include: water bath and bathless dissolution, media preparation (heating, degassing and dispensing) and disposal, in-situ fiber optic UV, bathless tablet disintegration, content uniformity and dissolution autosampling. Distek's bioprocessing portfolio includes the BIONE single-use bioreactor for cell culture applications, the BIONE 1250 bioreactor control system for both mammalian and microbial models and now the BIONE Mixing System for upstream and downstream benchtop applications. Distek's core market includes brand name, generic and biosimilar drug manufacturers, CRO's, CMO's, Nutraceuticals, government agencies and universities. Distek holds several instrumentation and accessory patents and has been ISO certified since 2002.

