DISTEK

BIOne MIXING SYSTEM

STANDARDIZE, OPTIMIZE & QUALIFY

Upstream and downstream process development teams now have a robust solution to replace rudimentary stir bar processes on their laboratory benchtops.

The BIOne Mixing System offers proven magnetic drive agitation, which supports streamlined process scaling based upon power input per unit volume, a well-established engineering principle.

The gamma irradiated BIOne Single-Use Vessels used within the BIOne Mixing System are assembled in Distek's ISO-7 certified cleanroom. Replacement of typical glass bottles with sanitized Single-Use Vessels can be a viable option for laboratory teams which are generating material for preclinical *in vivo* studies.

FEATURES, ADVANTAGES & BENEFITS

- 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 BIOne Single-Use Mixing Vessels are Assembled in Distek's ISO-7 certified Cleanroom helping to Reduce Product Pool Endotoxin Levels

APPLICATIONS

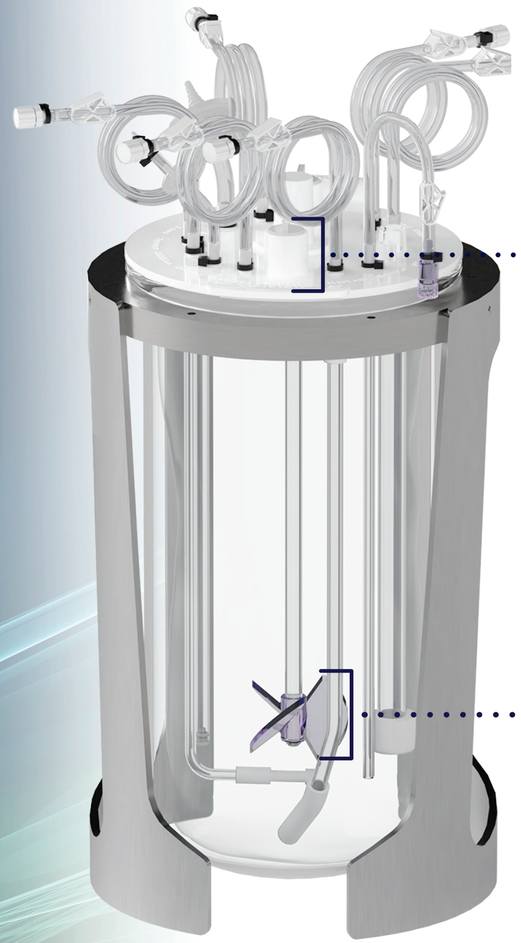
- Buffer Preparation
- Filtrate Collection
- Final Fill & Formulation
- Material Hold Validation
- Media Preparation
- Product Pool Adjustment

PROTECT PRODUCT INTEGRITY

- The Gamma Irradiated BIOne Single-Use Vessels used within the BIOne Mixing System are Assembled within an ISO-certified Cleanroom and can Help Reduce Product Pool Endotoxin Levels as Compared to Traditional Glass Vessels
- Highly Suitable Platform for Downstream Scale Down Modeling to Support Product Pool Hold Validation Studies and Product Stability Testing
  - Robust Temperature Control Down to 4°C
  - Weldable C-Flex Tubing and Luer-lock Fittings Provide Viable Solutions for Simple Process Sampling Operations

TECHNICAL SPECIFICATIONS	BIOne 2L SINGLE-USE VESSEL	BIOne 5L SINGLE-USE VESSEL
Working Volume (Maximum)	2L	5L
Working Volume (Minimum)	0.9L	1.7L
Operating Temperature Range	4°C to 60°C[1]	4°C to 60°C[1]
Operating Pressure (Maximum)	5 psig (.0345 mPa)	5 psig (.0345 mPa)
Agitation Range	15 to 450 rpm	15 to 450 rpm
Gamma Irradiated	Gamma Irradiated between 25 and 40 kGy	

[1] BIOne Single-Use Vessel materials rated for use in processes at temperatures up to 60°C. Structural Integrity Testing completed for operations up to 60°C. Leachable and Extractables Testing completed for operations up to 40°C.



BIOne SINGLE-USE VESSEL FEATURES

WELDABLE C-FLEX TUBING

Weldable Size 16 C-Flex Tubing facilitates Simple Aseptic Transfer Both Into and Out of the Vessel

PG-13.5 THREADED PORTS

Universal PG-13.5 Threaded Ports Support the Integration of Online Process Analytical Technologies (PATs)

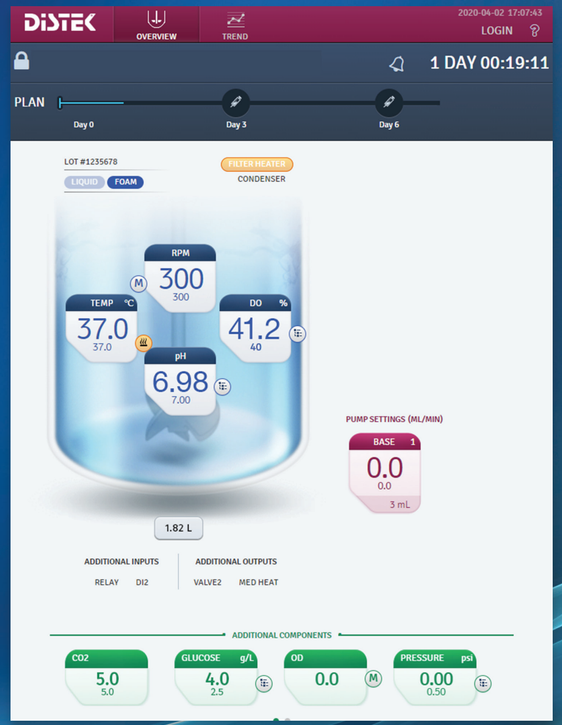
PITCHED BLADE IMPELLER

Reliable, Highly Scalable, Magnetic Drive Pitch Blade Impeller Agitation

EXPAND ONLINE PROCESS ANALYTICS

- Nearly Limitless Process Analytical Technology (PAT) Integration Potential using the BIOne Mixing System Additional I/O Option
  - 4 Analog Inputs
  - 4 Analog Outputs
  - 2 Digital Inputs
  - 2 Digital Outputs

- Transition to Higher Level Process Characterization through the Integration of Supplemental Online Analytical Probes and Devices
  - Conductivity Sensors (ion concentration)
  - Turbidity Sensors (product pool clarity)
  - Optical Density Sensors (contamination detection)
  - Differential Pressure Sensor (monitoring integrity of filtration processes)



BIOne

POWERFUL DATA TRENDING

PROCESS TREND DATA

- Remove the need for *cold room chart recorders* using the onboard data trending capabilities of the BIOne Mixing System
- Record up to 30 days of process data, with timepoints every 30 seconds
- *Data Export* function allows for files to be easily uploaded to ELNs in .CSV formats

ADDITIONAL TRENDING FEATURES

- Compare Feature allows for current online data to be compared to previous runs in real-time
- Events Feature allows for real-time process documentation of specific time points

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Distek, founded in 1976, has established itself as a leading provider of benchtop laboratory instruments for the pharmaceutical and biotechnology industries. Our introduction of the BIOne product line in 2016 marked our strategic expansion into bioprocessing, beginning with the innovative BIOne Single-Use Bioreactor.

A standout in our bioprocessing line is the BIOne 1250 bioprocess controller, a recipient of the 2019 IDEA award, reflecting our commitment to excellence in design and functionality. More recently, we have expanded our bioprocessing solutions with the launch of the BIOne 250 for Microbial Applications and the BIOne Mixing System, further broadening our support for biotechnology research and production needs.

Our mission revolves around exceeding customer expectations through innovation, quality, and support, driving Distek's growth and continuous improvement. With over four decades of experience, our core markets include brand name, generic and biosimilar drug manufacturers, CRO's, CMO's, cultured foods, Nutraceuticals, food & flavors, agriculture, beverage, government agencies and universities. Our commitment to innovation and quality is evidenced by our continuous ISO certification since 2002 and a robust portfolio of patents.

MADE IN USA

March 2024