



## BIOSTAT® CultiBag STR Innovative Fermentation



# Innovative Fermentation – Disposable Bioreactor, Sensor and Stirrer Technology

## **BIOSTAT® CultiBag STR... Stirred not Shaken**

The BIOSTAT® CultiBag STR is a new line of stirred tank bioreactors. The system is comprised of a stainless steel support housing, a single use bioreactor chamber and a superior control system utilizing disposable sensors. The BIOSTAT® CultiBag STR is the first completely disposable and scalable solution in the fermentation | bioreactor market. Available in two configurations; the basic BIOSTAT® CultiBag STR and the advanced BIOSTAT® CultiBag STR Plus, the system offers an excellent solution for every budget and every need.

Single use systems have many advantages over reusables in terms of reduced maintenance, reduced overhead expenses and reducing or eliminating the need for:

- Sterilization in Place (SIP)
- Cleaning in Place (CIP)
- Water for Injection (WFI)
- User time and effort
- Validation requirements
- Risk of cross contamination

The disposable cultivation vessel, CultiBag STR is very similar to conventional stainless steel systems, in terms of geometry and design. Set up is simple and hassle free. For support the CultiBag STR is installed in a stainless steel housing. Single use sensors come preinstalled and presterilized with the bag – thereby avoiding risky insertion of traditional probes.

The CultiBag STR is a flexible cultivation chamber offering a broad range of connectors, tubings, impellers and sparger designs, which are preinstalled in the bag. Connected to the motor via a magnetic coupling the culture system stays closed and sterile at all times. Bag geometry and aspect ratio remain the same at increasing scale, making the transition from traditional stainless steel to single use as easy as possible.

The BIOSTAT® STR Control Tower features best-in class control capabilities utilizing disposable sensors with feedback control. Disposable pH and DO sensors replace the traditional labor intensive polarographic and galvanic sensors but assure the same level of control which is already state of the art in reusable systems. An optical fiber connects to the sensor patch through a sterile barrier at the end of a sleeve in the bag – sterility is maintained at all times. The optical fiber transmits light of specific wavelength to the sensor and returns the luminescence response from the sensor back to the measuring amplifier. Calibration is fast and easy.

An exceptional gas mixing strategy has been designed in cooperation with multiple world leading biopharmaceutical companies. It is operated via a simple and intuitive touch screen which keeps staff training to a minimum. The compact design of the stainless steel housing reduces the footprint and saves precious laboratory space.

### **BIOSTAT® CultiBag STR is ideal for:**

- Cell culture applications
- Industrial and academic research
- Process development
- Process optimization
- Pilot scale production
- Seed cultivation for large scale bioreactors
- Production scale





The BIOSTAT® CultiBag STR Plus is available in both single and twin controller configuration. It increases flexibility and allows control of two separate cultivations at the same time but independently from each other.

#### Features:

- Pre-defined configuration packages available
- Completely disposable bio-reactor in a traditional design
- Aspect Ratio (H:D) 2:1
- User-friendly touch screen interface for easy operation
- Trend display with up to 6 process values
- Top driven Stirrer with magnetic coupling
- Application driven integrated gassing systems
- Control of agitation speed, pH, DO, temperature, substrate addition, gasmix and gas flow via optional Mass Flow Controllers (MFC)
- Available as single and twin version
- Complete qualification support package available
- Disposable optical DO & pH sensors for measurement
- pH & DO recalibration
- Overpressure safety shutdown
- BioPAT® MFCS/DA data logging software included
- Choice between 6-blade and 3-blade impellers
- Overlay & Sparger aeration with ring- or microsparger
- Heating blankets for only heating or Jacketed vessel with cooling water for heating | cooling

#### Technical Specifications

##### Hardware dimensions W × H × D (mm)

##### BIOSTAT® CultiBag STR, single wall

BIOSTAT® CultiBag STR 50L  
1723 × 1663 × 754

BIOSTAT® CultiBag STR 200L  
1723 × 1663 × 754

##### BIOSTAT® CultiBag STR Plus, single or double wall

BIOSTAT® CultiBag STR Plus 50L  
1723 × 1663 × 754

BIOSTAT® CultiBag STR Plus  
200L  
1723 × 1663 × 754

BIOSTAT® CultiBag STR Plus  
50L | 50L  
2652 × 1663 × 754

BIOSTAT® CultiBag STR Plus  
200L | 200L  
2652 × 1663 × 754

BIOSTAT® CultiBag STR Plus  
50L | 200L  
2652 × 1663 × 754

# ...The First Disposable Bioreactor in a Traditional Stirred Tank Design



## **BIOSTAT® STR Control Tower**

The Control Tower is available in two different configurations, the basic BIOSTAT® STR Control Tower and the advanced BIOSTAT® STR Control Tower Plus. They are equipped with all necessary measurement and control hardware, including pumps and gassing systems.



## **Skid**

The BIOSTAT® CultiBag STR consists of a BIOSTAT® STR Control Tower skid and a bag holder skid. The BIOSTAT® CultiBag STR Plus Twin system consists of two bag holder skids which can be connected to one BIOSTAT® STR Control Tower Plus.

During operation the bag holder and Control Tower skid are easily connected to each other for a quick and space saving system combination. After cultivation the bag holder skid can be disconnected and transported for further production steps such as harvesting and purification. The BIOSTAT® STR Control Tower is immediately ready to start a new cultivation by connecting it to the next bag holder skid. This flexibility transforms the cultivation process into a continuous process without delays due to harvesting, cleaning or purification steps.



## **Intuitive Touch screen**

The control system features an intuitive "easy-to-use" TFT touch screen display for excellent local operation and process control. It is validatable and developed according to good automation manufacturing practice guidelines (GAMP). Intuitive screens allow for an excellent process value overview and operation. Proven industrial control hardware ensures reliable system performance.



## **Gassing System**

The gassing system has been developed in cooperation with multiple world leading biopharmaceutical companies. Its high level functionalities make the BIOSTAT® CultiBag STR a powerful tool for all your application demands. It allows individual flow rates and gas mixing for each cultivation chamber. Flow rates are adjustable via precision flow meters. In addition to that integrated mass flow controllers assist in gaining optimal process control. Gasses can be routed to overlay or sparger as required.

Cell culture packages are supplied with an integrated 4-gas mixing system for Air, O<sub>2</sub>, CO<sub>2</sub> and N<sub>2</sub>.

For any further details, please refer to our BIOSTAT® CultiBag STR and BIOSTAT® CultiBag STR Plus Datasheets.



### Temperature Control

Two different ways of controlling temperature are possible: heating only or heating | cooling.

### Heating Only

Powerful heating blankets around the stainless steel housing, allowing excellent temperature control via active heating. Temperature range from room temperature to 40°C is possible

### Heating | Cooling

A combination of an electrical heater with a jacketed vessel where recirculation of cooling water happens, allows for fast heat up and cool down of your process. Temperature range from 8°C above cooling water to 40°C is possible.

### Agitation

A powerful high performance motor drive combines low-shear agitation with excellent mixing. The motor assures quiet operation and provides convenient handling. The stirrer is magnetically linked to the motor drive ensuring safe and sterile connection. It also purges the risk of damage during stirring.



### Dosing pumps

Up to five industrial proven, easy-to-use peristaltic pumps can be integrated in the system. They can be used for addition of corrective agents, feeding purposes as well as control of the culture volume. Alternatively up to 2 of these may be replaced by external pumps.



### Bag Holder

For additional convenience the bag holder is installed on a separate skid. It may be disconnected from the controller skid after cultivation and can be transferred to the next step of the production process. At the same time another bag holder skid can be connected to the controller to start a new run right away.

Installation of a disposable cultivation chamber has never been so easy. The cylindrical holder is designed as 2 hemispheres which can be opened for installation of the bag. Furthermore, the CultiBag STR and its bag holder have been developed as a perfect match, which makes closing the cylinder after installation of the CultiBag STR very convenient.



### Disposable Cultivation Chamber

The CultiBag STR design is based on a traditional reusable bioreactor vessel. Total bag volume aspect ratio (H:D) is 2:1. This makes the transfer from reusable to disposable processes. The CultiBag STR is available in a working volume range of 12.5 to 200 L. A broad range of bag sizes allowing for the complete scalability from R&D over pilot to large-scale production applications will be available shortly.

All aeration and exhaust lines are equipped with 0.2 µm grade sterile membrane cartridges. Furthermore, a large number of ports for feeding, harvesting and sampling are installed both on the top, on the lower front and the bottom side of the bag.

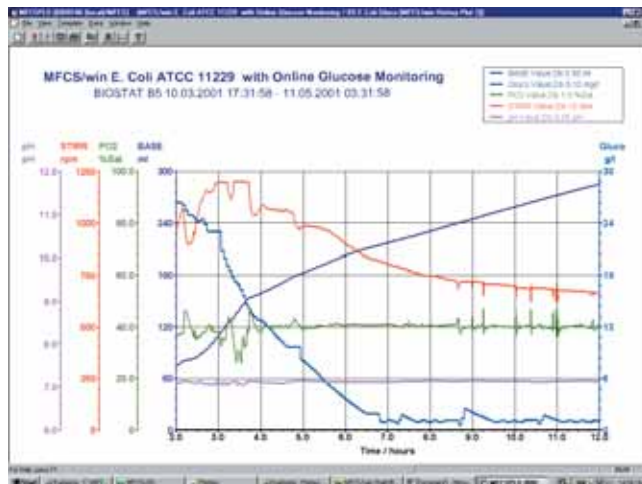
Disposable optical sensors for pH and DO are pre-installed and pre-calibrated for precise measurement and control.

The design is highly flexible due to a large choice of impellers, sparging lines, connectors and tubing.



# ... Advanced process control for ideal culture conditions

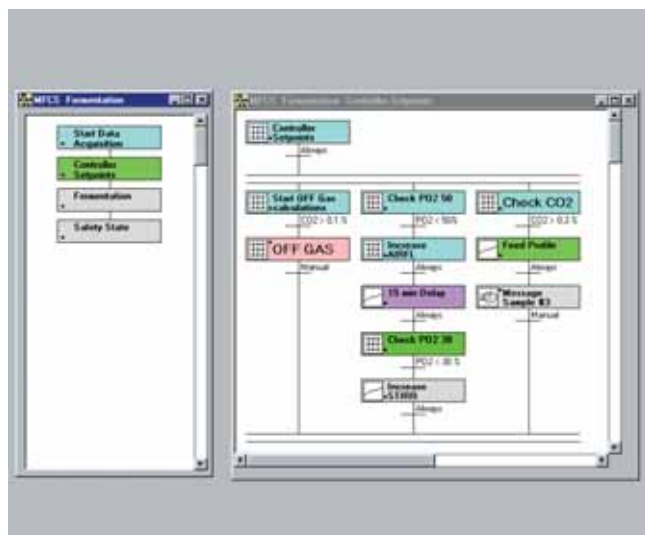
BioPAT® MFCS/win:  
Comprehensive plot  
and report functions



## Features:

- Up to 4 process units
- Batch oriented software package
- Sample Data Management
- Enhanced Plotting
- Export functions
- Easy to use programming interface

Advanced functionality for supervisory process control and data acquisition is provided by BioPAT® MFCS/win, a feature-rich GAMP category 4 software package. It is capable of supporting the most demanding research or production environments, including S88- and 21CFR11-compliance as well as OPC connectivity. Multi-user network access to up to 16 process units and remote alarming are additional features. Please contact your local Sartorius Stedim Biotech representative for further details.



BioPAT® MFCS/win: Batch recipe according to ISA-S88

## BioPAT® MFCS

BioPAT® MFCS/DA is delivered with every BIOSTAT® CultiBag STR package. It is ideal for capturing, storing and visualizing process data as well as research & development settings. Batch-oriented bio-processing is the key aspect in our data management software. Therefore, all batch-related data are stored under a unique batch name | ID.

The Sample Data Management module simplifies the inclusion of external, manually-entered data (e.g. glucose analyzer, cell density, etc.) into your batch record. Visualization of the batch data is realized by a powerful plotting function, allowing for multiple variables as well as the comparison of multiple batches simultaneously. The export function may be used to export batch data to other data analysis programs.

BioPAT® MFCS SCADA (Supervisory control and data acquisition) ensures total process safety, when used in combination with the basic BIOSTAT® STR Control Tower or the advanced BIOSTAT® STR Control Tower Plus for local process control.

## Technical Specifications

Description	Hardware			
	BIOSTAT® CultiBag STR 50L	BIOSTAT® CultiBag STR Plus 50L	BIOSTAT® CultiBag STR 200L	BIOSTAT® CultiBag STR Plus 200L
<b>Volume</b>				
Total Volume	70 L	70 L	280 L	280 L
Minimum Working Volume	12.5 L	12.5 L	50 L	50 L
Maximum Working Volume	50 L	50 L	200 L	200 L
<b>Power Supply</b>				
208 VAC	×	×	×	×
400 VAC	×	×	×	×
<b>Bag Holder</b>				
Installed on skid	×	×	×	×
Electro-polished	×	×	×	×
Hemispherical doors	2	2	2	2
Holder for Air filters	×	×	×	×
Temperature Control	Only Heating	Only Heating or Heating   Cooling	Only Heating	Only Heating or Heating   Cooling
Viewing window	×	×	×	×
Opening for sideports	×	×	×	×
pT 100 probe	1	1	1	1
Sensor Clamps	3	3	3	3
Filter Heater	1	1	1	1
Top drive motor	1	1	1	1
<b>Control Tower</b>				
Single version	×	×	×	×
Twin version	–	×	–	×
Installed on skid	×	×	×	×
Temperature Control, Single Wall	RT – 40°C	RT – 40°C	RT – 40°C	RT – 40°C
Temperature Control, Double Wall	–	8°C above cooling water – 40°C	–	8°C above cooling water – 40°C
Stirrer Speed	20 – 150 rpm	20 – 150 rpm	20 – 150 rpm	20 – 150 rpm
pH control	5.5 – 8.5	5.5 – 8.5	5.5 – 8.5	5.5 – 8.5
DO control	0 – 100%	0 – 100%	0 – 100%	0 – 100%
<b>Amplifiers for:</b>				
– Disposable DO sensor	×	×	×	×
– Disposable pH sensor	×	×	×	×
– Reusable DO sensor	(x)	(x)	(x)	(x)
– Reusable pH sensor	(x)	(x)	(x)	(x)
– Temperature	×	×	×	×
Cascade Control	×	×	×	×
<b>Recalibration function for:</b>				
– Disposable DO sensor	×	×	×	×
– Disposable pH sensor	×	×	×	×

Description	Hardware			
	BIOSTAT® CultiBag STR 50L	BIOSTAT® CultiBag STR Plus 50L	BIOSTAT® CultiBag STR 200L	BIOSTAT® CultiBag STR Plus 200L
<b>Interface:</b>				
- Ethernet	×	×	×	×
- RS232	4	4	4	4
- External	4	4	4	4
BioPAT® MFCS/DA	×	×	×	×
<b>Gassing module</b>				
<b>Rotameter [L/min]:</b>				
<b>Sparger Line</b>				
- O <sub>2</sub>	0.53 – 5.3	0.53 – 5.3**	2.3 – 23	2.3 – 23**
- N <sub>2</sub>	0.53 – 5.3	0.53 – 5.3**	2.3 – 23	2.3 – 23**
- CO <sub>2</sub>	0.53 – 5.3	0.53 – 5.3**	2.3 – 23	2.3 – 23**
- Air	0.53 – 5.3	0.53 – 5.3**	2.3 – 23	2.3 – 23**
<b>Overlay Line</b>				
- Air	0.53 – 5.3	0.53 – 5.3**	2.3 – 23	2.3 – 23**
- CO <sub>2</sub>	0.53 – 5.3	0.53 – 5.3**	n/a	2.3 – 23**
<b>MFC for:</b>				
<b>Sparger Line</b>				
- O <sub>2</sub>	(0.1 – 5.0)*	(0.1 – 5.0)** ***	(0.4 – 20)*	(0.4 – 20)** ***
- N <sub>2</sub>	-	(0.1 – 5.0)** ***	-	(0.4 – 20)** ***
- CO <sub>2</sub>	-	(0.1 – 5.0)** ***	-	(0.4 – 20)** ***
- Air	(0.1 – 5.0)*	(0.1 – 5.0)** ***	(0.4 – 20)*	(0.4 – 20)** ***
<b>Overlay Line</b>				
- Air	-	(0.1 – 5.0)** ***	-	(0.4 – 20)** ***
- CO <sub>2</sub>	n/a	(0.1 – 5.0)** ***	n/a	(0.4 – 20)** ***
<b>Soft Button for:</b>				
CO <sub>2</sub>	×	-	×	-
N <sub>2</sub>	-	(×)	-	(×)
O <sub>2</sub>	-	(×)	-	(×)
<b>Pumps &amp; Balances</b>				
Peristaltic Pumps	2	3 per side	2	3 per side
Additional Pumps	(up to 2)	(up to 2 per side)	(up to 2)	(up to 2 per side)
Balances	(up to 2)	(up to 2 per side)	(up to 2)	(up to 2 per side)

\* MFC for Air Sparger and O<sub>2</sub> for BIOSTAT® CultiBag STR can only be ordered as one set and not separately

\*\* Alternative flow ranges are available on request

\*\*\* For BIOSTAT® CultiBag STR Plus up to 6 MFC can be ordered separately

( ) optional, needs to be ordered separately





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