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biotech

## BIOSTAT<sup>®</sup> CultiBag STR Innovative Fermentation



turning science into solutions

# 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

#### Dimensions & Weight

##### BIOSTAT® CultiBag STR 200:

###### Skid with Bagholder 200

Dimensions W×H×D:  
926×1641×752 mm

Weight: 150 kg

###### Skid with BIOSTAT® STR Control Tower

Dimensions W×H×D:  
340×1450×600 mm

Weight: 150 kg

##### BIOSTAT® STR Control Tower

Dimensions W×H×D:  
340×1300×600 mm

Weight: 100 kg

##### BIOSTAT® CultiBag STR 200 plus:

###### Skid with Bagholder 200

Dimensions W×H×D:  
926×1641×752 mm

Weight: 150 kg

###### Skid with BIOSTAT® STR Control Tower plus

Dimensions W×H×D:  
340×1450×600 mm

Weight: 150 kg

##### BIOSTAT® STR Control Tower plus

Dimensions W×H×D:  
340×1300×600 mm

Weight: 100 kg

# ...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 200 and BIOSTAT® CultiBag STR 200 Plus Datasheets.



#### **Temperature Control**

Temperature control is performed via powerful heating blankets around the stainless steel housing, allowing excellent temperature control. A closed loop water thermostat system for heating and cooling will become available shortly.

#### **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 which ensures a safe and sterile connection. It also purges the risk of damage during stirring.



#### **Dosing pumps**

Up to four 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 50 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 come available shortly.

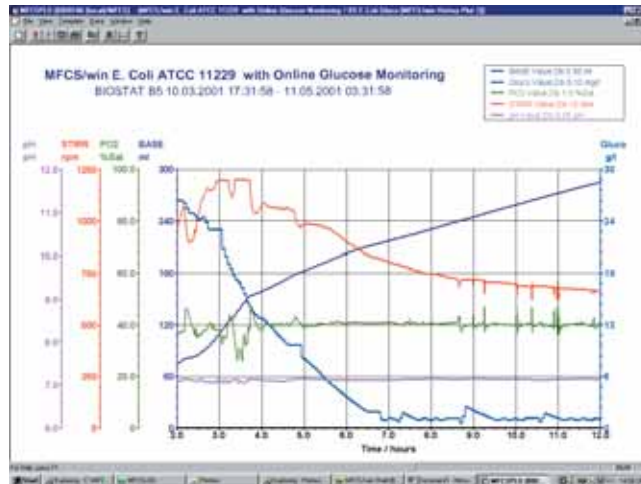
All aeration and exhaust lines are equipped with 0.2  $\mu\text{m}$  grade sterile membrane cartridges. Furthermore, a large number of ports for feeding, harvesting and sampling are installed both on the top, on the lower front and the bottom side of the bag.

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

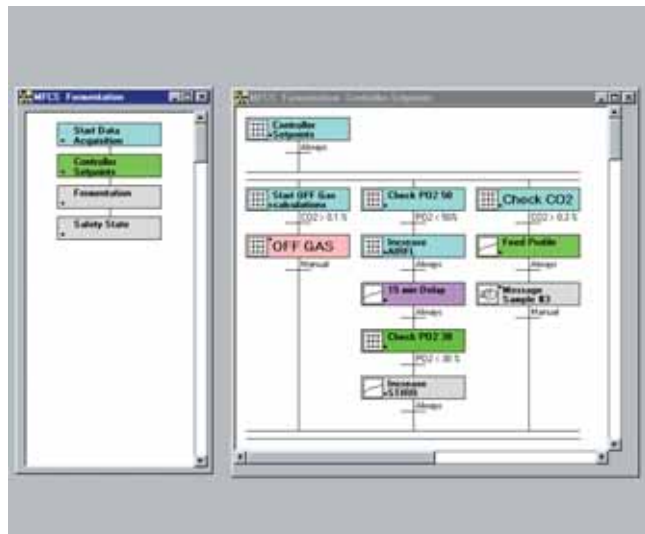
BioPAT® MFCS/win:  
Comprehensive plot  
and report functions



## 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

Using the basic BIOSTAT® STR Control Tower or the advanced BIOSTAT® STR Control Tower Plus for local process control, in combination with our superior process control software BioPAT® MFCS SCADA (supervisory control and data acquisition) ensures total process safety.

## 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.

## Technical Specifications

Description	Hardware	
	BIOSTAT® CultiBag STR 200	BIOSTAT® CultiBag STR 200 Plus
<b>Volume</b>		
Total Volume	280 L	280 L
Minimum Working Volume	50 L	50 L
Maximum Working Volume	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
Holder for Air filters	×	×
Heating blanket	2	2
Viewing window	×	×
Opening for sideports	×	×
pT 100 probe	1	1
Sensor Clamps	3	3
Filter Heater	1	1
Top drive motor	1	1
<b>Control Tower</b>		
Single version	×	×
Twin version	–	×
Installed on skid	×	×
Temperature Control	RT – 40°C	RT – 40°C
Stirrer Speed	20 – 150 rpm	20 – 150 rpm
pH control	5.5 – 8.5	5.5 – 8.5
DO control	0 – 100%	0 – 100%
<b>Amplifiers for:</b>		
– Disposable DO sensor	×	×
– Disposable pH sensor	×	×
– Reusable DO sensor	(×)	(×)
– Reusable pH sensor	(×)	(×)
– Temperature	×	×
Cascade Control	×	×
<b>Recalibration function for:</b>		
– Disposable DO sensor	×	×
– Disposable pH sensor	×	×

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

\* MFC for Air Sparger and O<sub>2</sub> for BIOSTAT® CultiBag STR 200 can only be ordered as one set and not separately

\*\* For BIOSTAT® CultiBag STR 200 Plus up to 6 MFC can be ordered separately

( ) optional, needs to be ordered separately

# Sales and Service Contacts

For further contacts, visit [www.sartorius-stedim.com](http://www.sartorius-stedim.com)

## Europe

### Germany

Sartorius Stedim Biotech GmbH  
August-Spindler-Strasse 11  
37079 Goettingen

Phone +49.551.308.0  
Fax +49.551.308.3289

[www.sartorius-stedim.com](http://www.sartorius-stedim.com)

Sartorius Stedim Systems GmbH  
Schwarzenberger Weg 73-79  
34212 Melsungen

Phone +49.5661.71.3400  
Fax +49.5661.71.3702

[www.sartorius-stedim.com](http://www.sartorius-stedim.com)

### France

Sartorius Stedim Biotech S.A.  
Z.I. des Paluds  
Avenue de Jouques – BP 1051  
13781 Aubagne Cedex

Phone +33.442.845600  
Fax +33.442.845619

Sartorius Stedim France SAS  
ZI des Paluds  
Avenue de Jouques – CS 71058  
13781 Aubagne Cedex

Phone +33.442.845600  
Fax +33.442.846545

### Austria

Sartorius Stedim Austria GmbH  
Franzosengraben 12  
A-1030 Vienna

Phone +43.1.7965763.18  
Fax +43.1.796576344

### Belgium

Sartorius Stedim Belgium N.V.  
Leuvensesteenweg, 248/B  
1800 Vilvoorde

Phone +32.2.756.06.80  
Fax +32.2.756.06.81

### Denmark

Sartorius Stedim Nordic A/S  
Hoerskaetten 6D, 1.  
DK-2630 Taastrup

Phone +45.7023.4400  
Fax +45.4630.4030

### Italy

Sartorius Stedim Italy S.p.A.  
Via dell'Antella, 76/A  
50012 Antella-Bagno a Ripoli (FI)

Phone +39.055.63.40.41  
Fax +39.055.63.40.526

### Netherlands

Sartorius Stedim Netherlands B.V.  
Edisonbaan 24  
3439 MN Nieuwegein

Phone +31.30.6025080  
Fax +31.30.6025099

### Spain

Sartorius Stedim Spain SA  
C/Isabel Colbrand 10-12,  
Planta 4, Oficina 121  
Polígono Industrial de Fuencarral  
28050 Madrid

Phone +34.91.3586102  
Fax +34.91.3588804

### Switzerland

Sartorius Stedim Switzerland GmbH  
Lerzenstrasse 21  
8953 Dietikon

Phone +41.44.741.05.00  
Fax +41.44.741.05.09

### U.K.

Sartorius Stedim UK Limited  
Longmead Business Park  
Blenheim Road, Epsom  
Surrey KT19 9 QQ

Phone +44.1372.737159  
Fax +44.1372.726171

## America

### USA

Sartorius Stedim North America Inc.  
131 Heartland Blvd.  
Edgewood, NY 11717

Toll-Free +1.800.368.7178  
Fax +1.631.254.4253

Sartorius Stedim SUS Inc.  
1910 Mark Court  
Concord, CA 94520

Phone +1.925.689.6650  
Toll Free +1.800.914.6644  
Fax +1.925.689.6988

Sartorius Stedim Systems Inc.  
201 South Ingram Mill Road  
Springfield, MO 65802

Phone +1.417.873.9636  
Fax +1.417.873.9275

### Argentina

Sartorius Argentina S.A.  
Int. A. Avalos 4251  
B1605ECS Munro  
Buenos Aires

Phone +54.11.4721.0505  
Fax +54.11.4762.2333

### Brazil

Sartorius do Brasil Ltda  
Av. Dom Pedro I, 241  
Bairro Vila Pires  
Santo André  
São Paulo  
Cep 09110-001

Phone +55.11.4451.6226  
Fax +55.11.4451.4369

### Mexico

Sartorius de México S.A. de C.V.  
Circuito Circunvalación Poniente No. 149  
Ciudad Satélite  
53100 Naucalpan, Estado de México

Phone +52.5555.62.1102  
Fax +52.5555.62.2942

## Asia | Pacific

### China

Sartorius Stedim Beijing  
Representative Office  
No. 33, Yu'an Road,  
Airport Industrial Zone B, Shunyi District  
Beijing 101300

Phone +86.10.80426516  
Fax +86.10.80426580

Sartorius Stedim Shanghai  
Representative Office  
Room 618, Tower 1, German Centre,  
Shanghai, PRC., 201203

Phone +86.21.28986393  
Fax +86.21.28986392.11

Sartorius Stedim Guangzhou Office  
Room 704, Broadway Plaza,  
No. 233-234 Dong Feng West Road  
Guangzhou 510180

Phone +86.20.8351.7921  
Fax +86.20.8351.7931

### India

Sartorius Stedim India Pvt. Ltd.  
10, 6th Main, 3rd Phase Peenya  
KIADB Industrial Area  
Bangalore – 560 058

Phone +91.80.2839.1963|0461  
Fax +91.80.2839.8262

### Japan

Sartorius Stedim Japan K.K.  
KY Building, 8-11  
Kita Shinagawa 1-chome  
Shinagawa-ku  
Tokyo 140-0001

Phone +81.3.3740.5407  
Fax +81.3.3740.5406

### Malaysia

Sartorius Stedim Malaysia Sdn. Bhd.  
Lot L3-E-3B, Enterprise 4  
Technology Park Malaysia  
Bukit Jalil  
57000 Kuala Lumpur

Phone +60.3.8996.0622  
Fax +60.3.8996.0755

### Singapore

Sartorius Stedim Singapore Pte. Ltd.  
10, Science Park Road, The Alpha  
#02-25, Singapore Science Park 2  
Singapore 117684

Phone +65.6872.3966  
Fax +65.6778.2494

### Australia

Sartorius Stedim Australia Pty. Ltd.  
Unit 17/104 Ferntree Gully Road  
Waverley Business Park  
East Oakleigh, Victoria 3166

Phone +61.3.9590.8800  
Fax +61.3.9590.8828