



sartorius stedim  
biotech

## BIOSTAT® B-DCU II Fully Flexible for Advanced Process Development



turning science into solutions

# BIOSTAT® B-DCU II – the power and flexibility to meet your process

The BIOSTAT® B-DCU II is a new generation of Fermentor| Bioreactor system, designed for meeting demanding requirements in both research and process development. A newly engineered control system launches many of its well-proven design features into a new era, offering unprecedented advantages for process development laboratories around the world. Unrivaled for scale-down and scale-up modeling of various culture processes, the BIOSTAT® B-DCU II provides a new level of power and flexibility.

The BIOSTAT® B-DCU II consists of the local BioPAT DCU control tower and can be configured with up to six supply towers, each providing independent control of the respective culture vessel. The controller allows additional vessels and supply towers to be added on-site without the need for external interfaces or expensive software upgrades.

The BioPAT DCU Control Tower provides advanced process control. Besides the standard measurement and control possibilities, advanced control features like pressure control, Constant Total Gas Flow Control, Gravimetric Feed and Harvest Control are possible. The fully user configurable  $pO_2$  controller is another example. It allows the selection of 5 out of up to 10 actuators. All actuators can be operated parallel or sequential for optimal process control. For process safety and advanced process documentation a 3-Level password module as well as a Logbook module is available.

Use of a unique, integrated, space-saving tower design enables up to six supply towers and the BioPAT DCU control tower to be fully incorporated in a system occupying less than 3 meters of bench space

For further enhancement of system performance, a powerful supervisory process control software MFCS/DA for extended visualization, data acquisition and trend display is inclusive.



# development needs

## BIOSTAT® B-DCU II is ideal for:

- Industrial research
- Process development
- Up- and Down-scale experiments
- Production process control
- Small scale production

## Application

- Growth and production studies of microbial, mammalian, insect and plant cells
- Culture media composition and optimization
- Upscale migration i.e. Transition from shaking flasks
- Downscale of production process for process optimization
- Small scale protein and Mab expression
- High cell density cultivation

## Features

- Powerful industry rated DCU-4 control system with 15" TFT color touchscreen
- Independent process control for up to six culture vessels
- 0.5 L to 10 L working volume UniVessel®, jacketed or single wall vessel design
- Measurement and Control opportunities of pH, pO<sub>2</sub>, Temperature, Foam, Level, Substrate addition, Gas Mixing, Agitation, Gravimetric Feed and Harvest Control, Constant Total Gas Flow Control, Vessel pressure, Redox and Turbidity
- Up to six integrated peristaltic pumps with choices for fixed and analogue speed pumps
- Choice of polarographic or optical pO<sub>2</sub>-sensors
- Superior gas mixing with up to 6 Rotameter and Mass Flow Controller
- Easy on-site Supply Tower | Culture vessel upgrade
- Choice of pre-configured systems or customize from an extensive list of options
- Improved connectivity of utilities and probes
- Easy upgrade of cell culture packages for multi-purpose use
- Inclusive Supervisory Process control software
- Validation support available, inclusive Logbook and 3-Level password protection



# Up Close or Configure your needs with B-DCU II



## Supply Tower

The supply tower incorporates all necessary supply devices for independent control of six culture vessels per tower.

All culture vessel|supply tower connections are designed for easy handling. For example, quick couplings for vessel jacket and exhaust cooler connections, direct probes and agitation motor connections.

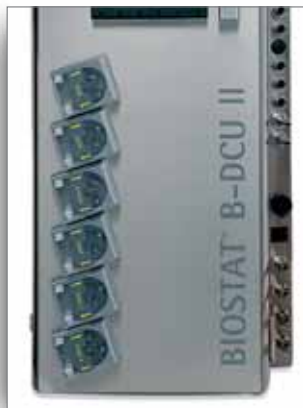
## Temperature Control

Each culture vessel can be operated and automatically controlled at different temperatures. There are two choices offered. For single wall vessels, there is an electric heating blanket and optional cooling finger with solenoid valve. Alternatively, an integrated, high-efficiency thermostat system – with recirculation pump combined with jacketed culture vessels – features precise temperature control, even at minimal working volumes.



## Gassing Systems

A variety of gassing systems are available for microbial and cell culture use. An easy upgrade of accessories also supports multi-purpose use. All systems provide individual flow rates and gas blending for each culture vessel. The flow rates are adjustable via precision rotameter, and a Thermal Mass Flow Controller is available as an option for each flow path. A safety valve is installed in each flow path to the culture vessel for vessel protection.



## Dosing Pumps

Up to six industrial proven, easy-to-use peristaltic pumps for each culture vessel are infinitely controlled for addition of corrective agents, feeding, as well as culturing volume control. Up to four of the six can be analogue speed controlled pumps. Several ranges are available for both fixed and speed controlled pumps. Additionally, external pumps for feeding can be easily connected.



## Agitation

The high performance Servo-drive motor assembly combines low shear, gentle agitation for cell cultures and high speed mixing for microbial high cell density cultivation, ensuring high oxygen transfer rates. The motor is gear-free for quiet operation – even at high speed ranges – and provides convenient handling due to the small size.



### Control Performance

The measurement and control capabilities supplied by Sartorius are second to none. The DCU-4 control system belongs to the most proven and advanced bioprocess controllers ever developed. Utilizing proven technology and expert engineering, our existing in-house systems to bring powerful control capabilities to the sophisticated biotechnology market.

Proven industrial control hardware ensures reliable system performance. The state of the art LAN Supply Tower|Control Tower connection reduces the needed wiring to a minimum.

Using a local controller for local process control in combination with a high level SCADA system ensures process control safety - even when PC problems exist.



### Intuitive Touchscreen

The control system presents an "intuitive-to-use", large TFT color touch screen for excellent local operation and process control for each of the up to six culture vessels.

Clearly designed screens provide an excellent process value overview and operation. Automatic single or group probe calibration routines reduce the manual operation needed to a minimum.



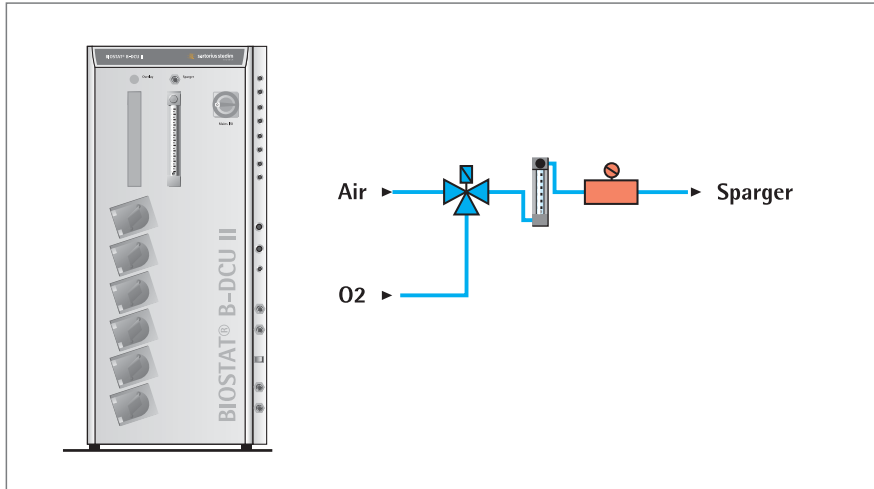
### Culture Vessel

Standard UniVessel® culture vessels, developed with over 40 years experience in up-scale and sterile design, are available as stirred tank vessels in 0.5, 1, 2, 5 and 10 L working volumes and as airlift vessels in 2 L and 5 L working volumes. The flexibility of the BIOSTAT® B-DCU II also allows for UniVessels® to be customized. Stainless steel and 15 L and 25 L single wall glass UniVessels® are available by special order to meet even the most extensive requirements.

All vessels are made of borosilicate glass with a stainless steel headplate. They have a round bottom design for optimal mixing results at low and high speed agitation. The polished stainless steel headplate has been specially designed for easy cleaning and maximized number of ports for probes and culturing accessories.

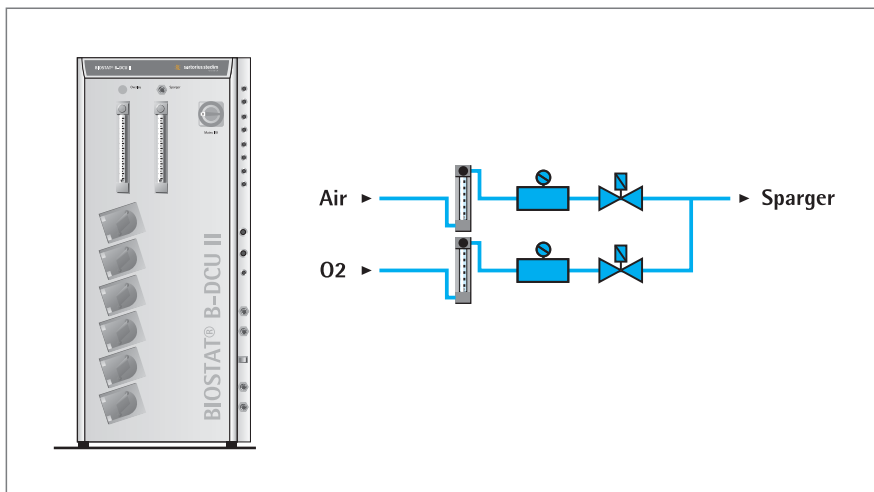
Each UniVessel® can be supplied with a range of accessories and devices, including flexible couplings to allow the vessels to fit into tight autoclaves.

# Choice of gassing strategies increase versatility










## O<sub>2</sub>-Enrichment

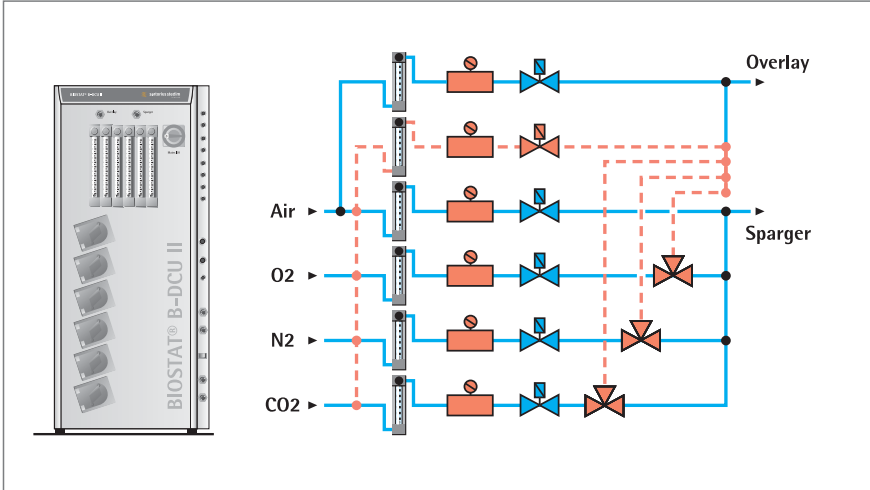
For microbial and insect cell culture applications and/or processes where cells exhibit a high oxygen (O<sub>2</sub>) requirement, aeration with air is usually no longer sufficient and additional oxygen has to be supplied. The O<sub>2</sub>-enrichment gassing strategy uses a 3-way solenoid valve to select either Air or O<sub>2</sub> flow to the sparger. Air is the default gas. O<sub>2</sub> is pulsed via the solenoid valve, flowing only when required to maintain the dissolved oxygen (DO) setpoint. Air is not provided at this time. A flow meter visually indicates and sets the Sparger flow rate. The O<sub>2</sub> can be switched from auto control to manual addition. A mass flow controller can be integrated to measure and control the total gas flow range via manual adjustment or automatically in conjunction with the DO controller. For example, Air total flow will be automatically increased up to a maximum; O<sub>2</sub> will be added instead of Air, if required.



## Gas Flow Ratio Control (GFRC)

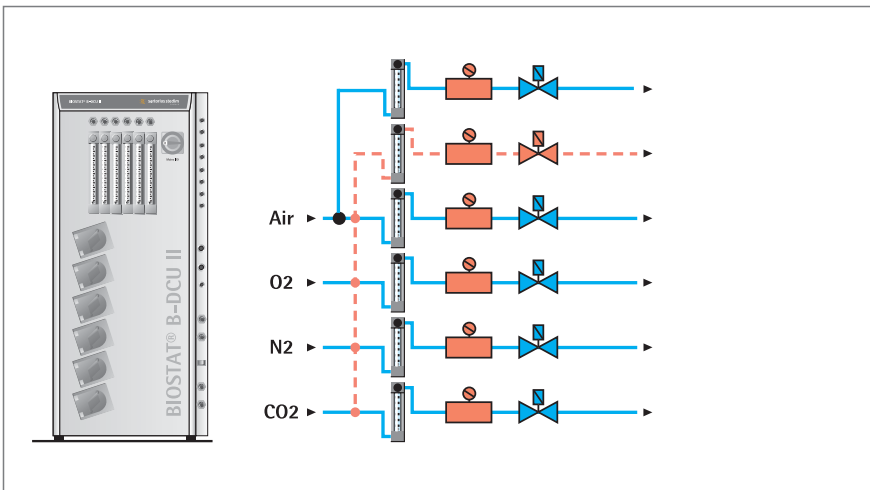
For microbial and insect cell culture applications and/or processes where cells exhibit a high oxygen (O<sub>2</sub>) requirement where more precise balancing of Air and O<sub>2</sub> is required. The Gas Flow Ratio Control gassing strategy utilizes two flow paths, each with mass flow controllers, one for Air and one for O<sub>2</sub> flow. Flow meters visually indicate the flow of Air and O<sub>2</sub>. Both mass flow controllers can be operated manually or automatically in conjunction with the DO controller. The DO controller can be user adjusted to keep e.g. the total flow or the ratio of the Air and O<sub>2</sub> constant.

-  Flow meter
-  optional Gas switch
-  Dosing shut-off valve
-  optional dosing shut-off valve
-  3-way dosing valve
-  optional Mass Flow Controller
-  Mass Flow Controller



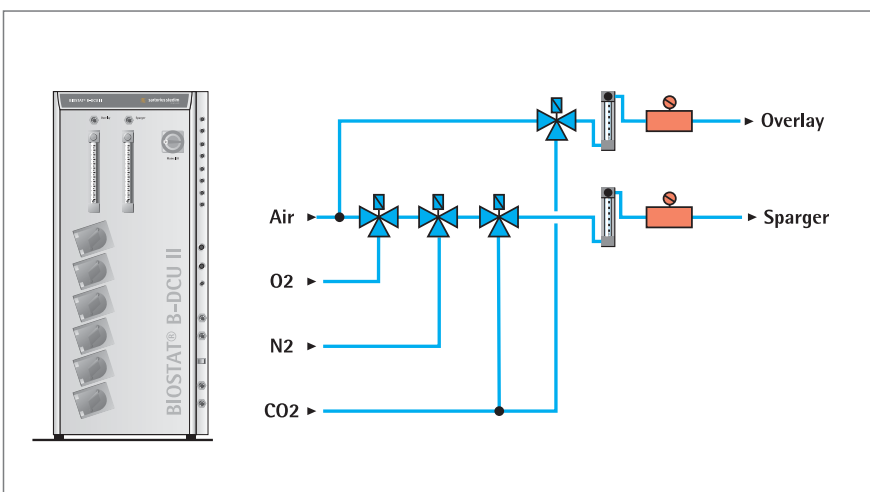
### Advanced Additive Flow – Two (2) gas outlets

For mammalian cell culture as well as multi-purpose use, Advanced Additive Flow - 2 gas outlets gassing strategy allows up to six gas flow paths. Solenoid valves select Air, O<sub>2</sub>, N<sub>2</sub> and CO<sub>2</sub> for simultaneous flow to the Sparger and Air to Overlay. Up to six flow meters visually indicate and set the flow rate for each gas. One additional gas flow path can be added to Sparger or Overlay outlet. Furthermore, two 3-way solenoid valves can be installed to switch the dedicated gas from Sparger to Overlay (incl. soft switch). The design does support the installation of up to six mass flow controllers, which makes Constant Sparger Gas Flow Control as well as Constant Overlay Gas Flow Control possible.



### Advanced Additive Flow – Six (6) gas outlets

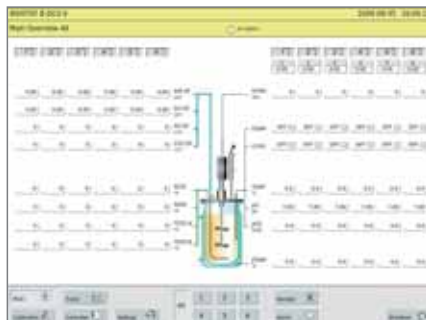
For mammalian cell culture as well as multi-purpose use, Advanced Additive Flow - 6 gas outlets gassing strategy allows up to 6 individual gas flow paths. Solenoid valves select Air, O<sub>2</sub>, N<sub>2</sub> and CO<sub>2</sub> for simultaneous and individual flow. The gas composition to Sparger and Overlay can be performed outside the gassing system by using T-connectors. Up to six flow meters visually indicate and set the flow rate for each gas. One additional gas flow path can be added. The design does support the installation of up to six mass flow controllers with shut off valves.



### Exclusive Flow

Used for in mammalian or insect cell culture, the Exclusive Flow module uses a series of 3-way solenoid valves to select either Air, O<sub>2</sub>, N<sub>2</sub> or CO<sub>2</sub> to flow the Sparger with Air as the default. Either Air or CO<sub>2</sub> also flows to Overlay. O<sub>2</sub>, N<sub>2</sub> and CO<sub>2</sub> can be switched from automatic to manual control. Flow meters for Sparger and Overlay visually indicate the flow of the selected gas. The design does support the use of mass flow controllers for total flow to Sparger and Overlay.

# BioPAT® automation solutions for advanced process control and documentation



Since the introduction in the late 80's of the first digital control unit (DCU) for biotech applications we have delivered several thousand digital controllers to leading pharmaceutical and biotech companies world-wide. The BioPAT® DCU controller belongs to the most proven, reliable and advanced bioprocess controller ever developed.

Use of a modular system design has enabled us to offer a broad range of flexible and cost-effective solutions for reusable and single use systems from R&D to production. BioPAT® DCU control systems are specially tailored for fermentation, cell culture and downstream processing like cross flow filtration applications.

As a result of our ongoing development activities, in close cooperation with leading biopharmaceutical companies the BioPAT® DCU system is now available in its 4th generation. The newly released firmware supports up to 200 process values, 128 control loops as well as 64 calibration routines.



Standard software provides full functionality for design and execution of all basic control functions including a superior process value overview in a simplified synoptic display, sensor calibration, in-process recalibration and control loop monitoring with alarm monitoring and trend display. In addition, a number of advanced features are implemented including an overview of all vessels or single vessel display, controller status indication, single or group calibration routines as well as a user configurable 5-step cascade DO control loop.

Furthermore, features like Gravimetric Flow Control for very precise feeding, Gravimetric Harvest Control as well as Total Gas Flow Control for constant gassing flows are further examples of the superior system performance. Its high level functionalities make all systems equipped with BioPAT® DCU control system a powerful tool for all your application demands.

BioPAT® DCU control systems allow for independent and simultaneous operation of multiple processes.

With classification as GAMP Category 4 (Configurable System), BioPAT® DCU is a validatable local control system which can be used in regulated cGMP production environments. A range of supporting functions, including multi-level password and operator logs, are available together with comprehensive documentation for validated systems.

All BioPAT® DCU systems are fully configurable by an optional available configuration tool. The ICE-Tool (Intelligent Configuration Environment) allows a user to easily configure, modify and save configurations, regardless of the complexity of their BioPAT® DCU system.



### **Data storage and visualization MFCS/DA**

For further enhancement of system performance, a powerful supervisory process control software MFCS/DA for extended visualization, data acquisition, data storage and trend display is included. MFCS/DA has been designed as "plug and play" to get started immediately. Batch-oriented bioprocessing is central to data management, therefore all batch-related data stored under a unique batch name.

MFCS/DA even includes the ability to incorporate other laboratory data, such as off-line process analyzers, using the Sample Data Management function. A Plotting module provides comprehensive features for further evaluation of measured bioprocess data, which together with an Export function gives added flexibility for analyzing data using other off-line programs. More advanced control strategies can be developed by the user using the Programmer's Interface. A typical application of this module could include calculation of Oxygen Uptake Rates (OUR), Carbon Dioxide Evolution Rate (CER) and Respiration Coefficient (RQ) for use in establishing new controller setpoints for more advanced process control.

The BIOSTAT® B-DCU II | MFCS/DA version provides simultaneous data acquisition and control of each supply tower.

### **Advanced SCADA software solution MFCS/win**

MFCS/win is specifically tailored to the requirements of fermentation and cell culture processes and includes functionality to fulfill requirements in research, pilot and production areas.

When used in combination with the BIOSTAT® B-DCU II the capabilities of the system can be extended with a number of additional features.

MFCS/win provides advanced functionality for supervisory process control and connectivity including on-line calculations, off-line calculations, batch reporting function, configuration management etc. as well as network access to multiple systems.

MFCS/win is designed as an open system, with an OPC (OLE for process control) interface, resulting in simple connectivity to third party software packages e.g. DOE Software for expanding the functionality of an entire system.

Batch management features, compliant with ISA-S88, allowing utilization of procedural batch control already on small systems, resulting in consistent process operation.

Fully validatable according to GAMP category 4 (Configurable System), MFCS/win has all the necessary functionality for operation in a regulated cGMP production environment and supports 21 CFR Part 11 compliance for electronic records and signatures.

A comprehensive driver library and OPC Client functionality are included for easy connection of and auxiliary process instrumentation.



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