BIOSTAT® D-DCU

Your “Fast Lane” to Production
Agenda

- Introduction
- System Overview
- Hybrid Solution
Drivers of Standardization for Stainless Steel Fermentation Systems

Key Drivers for Standardization

- Optimized and proven design
- Simplified and fast project execution
- Spare part availability
- Trained service technicians close to your operation
- Fast delivery
- Reduced costs
- Quickly up and running after commissioning
- Simplified process transfer from one site to the other
BIOSTAT® D-DCU
Ideal Platform for:

- Process development
- Process optimization
- Up-scale and down-scale
- Production
Agenda

- Introduction
- System Overview
- Hybrid Solution
BIOSTAT® D-DCU
Your “Fast Lane” to Production

BIOSTAT® D-DCU
- Standardized, fully-featured SIP | CIP -System
- Microbial and cell culture applications
- Process development to production
- Single or Twin configuration
- Working volumes 10L, 20L, 30L, 50L, 100L, 200L
- Hybrid process solutions for upstream

SIP: Sterilization in Place
CIP: Clean in Place
BIOSTAT® D-DCU
System Overview

Supply unit
- Open frame design
- Thermostat system
- Gas inlet
- Exhaust

Culture vessel
- Flat top plate
- Bottom agitation system
- Working volume 10 - 200L
- H : D ratio (total): 2 : 1 or 3 : 1
- Various top plate and side ports
- Sanitary TC sampling port

Control Tower
- Single or Twin configuration
- DCU control System
- Touch panel
- Integrated gassing system
- Integrated pumps
BIOSTAT® D-DCU

Control Tower

- Single or Twin Configuration
- 19” Color display with touch screen
- Industrial PC
- Integrated amplifier rack
- Integrated Gassing Module
  - Airflow (Microbial applications)
  - O2-Enrichment (Microbial applications)
  - Gas Flow Ratio Control (Microbial applications)
  - Advanced Additive Flow (Cell culture applications)
- Up to 6 integrated pumps per vessel
- Agitation motor controller

For Twin Configuration please note:
Both vessels may need to be sterilized at the same time since different compressed air settings are may be required for fermentation and sterilization.
“Airflow”

- Rotameter for Sparger flow
- Intermittent sparging of air controlled by DOT controller
- Option: DOT control via mass flow controller

Flow meter
optional Mass Flow Controller
Dosing shut-off valve
**BIOSTAT® D-DCU**

**Gassing Strategy**

- **“O2-Enrichment”**
  - Gassing system with O2 enrichment capability via solenoid valve
  - Rotameter for Total Sparger flow
  - Intermittent O2 enrichment controlled via DOT controller
  - **Option:** Mass Flow Controller for Total Sparger Flow

![Diagram](image)

- Flow meter
- 3-way dosing valve
- Optional Mass Flow Controller
- Dosing shut-off valve
**Gas Flow Ratio Control**

- Air flow gassing system with O2 supplementation capability via mass flow controller for Air and O2
- Continuous gas flow control of Air and Oxygen via DOT controller
- Rotameter for Total Sparger flow
- O2 Supplementation automatically controlled via pO2 controller
“Advanced Additive Flow”

- Mixing of up to four gases
  Air, N2, O2 and CO2
- Sparger and Overlay gas outlets
- Air, O2, N2, CO2 routed to Sparger, Air routed to Overlay
- Intermittent or Continuous gas flow control of Air, O2 and N2 via DOT controller
- Intermittent or Continuous gas flow control of CO2 via pH controller
- Each flow path with flow meter
- Each flow path with dosing/shut off valve
- **Option:** 6th flow path
- **Option:** Gas switch Sparge or Overlay
- **Option:** Up to 6 mass flow controller
BIOSTAT® D-DCU
Pumps

Integrated Pumps

• Up to 6 integrated peristaltic pumps per vessel
  - 1 & 2 fixed speed, on/off controlled
  - 3 & 4 fixed speed, on/off controlled or speed controlled
  - 5 & 6 speed controlled

• Watson Marlow pump heads

• Available pumps
  - fixed speed WM 114, 5 rpm
  - fixed speed WM 114, 44 rpm
  - speed controlled WM 114, 0.1–200 rpm
  - speed controlled WM 314, 0.1–200 rpm

• 2 x Connector for external speed controlled pumps per vessel
BIOSTAT® D-DCU
Human Machine Interface (HMI)

Human Machine Interface (HMI)

- Intuitive to use
- Touch panel
- 19” TFT display
- Swivel-mounted
Control Tower – Operation Main

- Vessel process value overview at a glance for Twin systems
- Unit vessel detail process value overview
- Controller status indication
  - O2 0.0 %
  - manual
  - O2 0.0 %
  - auto
  - O2 0.0 %
  - auto cascade
Control Tower - Operation Trend Display

- Up to 8 process variables
- Display time selectable:
  - 1 hour
  - 12 hours
  - 72 hours
- Selectable ranges:
  - for each process value
  - % value of measurement range
- Temporary storage only
Control Tower – Operation Calibration

- Single or Group calibration
- User guided calibration routines
- For pH, DOT, turbidity, redox probes
- For pumps (flow totalizer)
- For gas solenoids (gas totalizer)
Control Tower Operation – Controller

- Operations
  - Mode selection
  - Servo controller selection
  - Set point changes
  - Parameter changes
    - min./max. output
    - PID parameter
    - Dead band
  - Alarm setting
Advanced pO2 Controller

- Up to 4 servo controllers
- Free user configurable polyline for parallel or sequential control
- Starting points are depending on DOT controller output
- Selectable starting points
Control Tower - Operation Phases

Sequence control with interlocks for

- Sterilization
  - Full vessel, incl. gas inlet and exhaust line
  - Empty vessel incl. gas inlet and exhaust line
  - 4-Valve addition array
  - Separate Exhaust filter line
  - Sampling valve
  - Darin valve
  - Transfer group

- WIT test with external filter check system
- CIP sequence
- Valve switch
## BIOSTAT® D-DCU Measurement and Control Capabilities

<table>
<thead>
<tr>
<th>Measurement / Control</th>
<th>Measurement</th>
<th>Control</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agitation speed</td>
<td>X</td>
<td>X</td>
<td>Servo drive</td>
</tr>
<tr>
<td>Temperature</td>
<td>X</td>
<td>X</td>
<td>Controlled via closed loop thermostat system</td>
</tr>
<tr>
<td>pH_1 &amp; pH_2</td>
<td>X</td>
<td>X</td>
<td>Controlled via CO2 (Solenoid) or MFC / Acid pump + Base pump (analogue or digital)</td>
</tr>
<tr>
<td>pO2_1 &amp; pO2_2</td>
<td>X</td>
<td>X</td>
<td>Controlled via agitation speed; O2/ N2 supplementation (solenoid or MFC); Substrate; Pressure</td>
</tr>
<tr>
<td>(Clark or Optical)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foam</td>
<td>X</td>
<td>X</td>
<td>Conductivity probe</td>
</tr>
<tr>
<td>Level</td>
<td>X</td>
<td>X</td>
<td>Conductivity probe</td>
</tr>
<tr>
<td>Redox</td>
<td>X</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Vessel pressure</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Vessel weight</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Turbidity (Cell density)</td>
<td>X</td>
<td>X</td>
<td>Fundalux II</td>
</tr>
<tr>
<td>Substrate A &amp; B &amp; C &amp; D</td>
<td>(X)</td>
<td>X</td>
<td>Control of internal unused or additional optional peristaltic pump (internal or external)</td>
</tr>
<tr>
<td>via GFC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External signals</td>
<td>X</td>
<td>-</td>
<td>For connection of external amplifier</td>
</tr>
<tr>
<td>MFC 1....6 (Air, N2; O2; CO2)</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Balances 1....4</td>
<td>X</td>
<td>0</td>
<td>For Gravimetric Flow Control or addition vessel weight measurement</td>
</tr>
</tbody>
</table>

Other measurements and control can be implemented according to customer specification e.g. CO2 in liquid, exhaust (O2 & CO2), etc.
Supply Unit

Open frame design with...

- Gas inlet and Exhaust line
- Thermostat system
  - Closed-loop pressurized water system with circulation pump and heat exchanger for cooling
  - Heating
    : 10-30L: Alternatively via stainless steel heat exchanger (copper soldered) or electrical heating for fermentation and sterilization.
    Please note: Empty vessel sterilization requires clean steam supply
    : Option: Stainless steel heat exchanger (stainless steel welded)
    : 50-200L: Auxiliary electrical heater available (for process temp control only)

- Temperature control range
  - 8 °C above cooling water up to 90 °C
- Sterilization temperature
  - up to 130 °C
**BIOSTAT® D-DCU**
Supply Unit Components: 10–30L

1. Pressure control valve
2. Sight glass buffer system DMS
3. Temperature control system
   3a. Pressure compensation vessel
   3b. Safety valve
   3c. Circulation pump
   3d. Heat exchanger
   3e. Variant: Electrical heating
4. Variant: Dual exhaust filter line
5. Exhaust cooler
6. Gas inlet filter “Sparger”
7. Safety valve / Bursting disc w/ flow tube
8. Gas inlet filter “Overlay”
9. Culture vessel
10. Piping frame on casters
11. PV-Box w/ electrical and pneumatic components
### BIOSTAT® D-DCU Supply Unit Components: 50-200L

<table>
<thead>
<tr>
<th>Number</th>
<th>Component Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pressure control valve</td>
</tr>
<tr>
<td>2</td>
<td>Sight glass buffer system DMS</td>
</tr>
<tr>
<td>3</td>
<td>Temperature control system</td>
</tr>
<tr>
<td>3a</td>
<td>Pressure compensation vessel</td>
</tr>
<tr>
<td>3b</td>
<td>Safety valve</td>
</tr>
<tr>
<td>3c</td>
<td>Circulation pump</td>
</tr>
<tr>
<td>3d</td>
<td>Heat exchanger</td>
</tr>
<tr>
<td>3e</td>
<td>Auxiliary electrical heater</td>
</tr>
<tr>
<td>3f</td>
<td>Continues controlled steam valve</td>
</tr>
<tr>
<td>4</td>
<td>Exhaust filter</td>
</tr>
<tr>
<td>5</td>
<td>Exhaust cooler</td>
</tr>
<tr>
<td>6</td>
<td>Gas inlet filter &quot;Sparger&quot;</td>
</tr>
<tr>
<td>7</td>
<td>Safety valve / Bursting disc w/ flow tube</td>
</tr>
<tr>
<td>8</td>
<td>Gas inlet filter &quot;Overlay&quot;</td>
</tr>
<tr>
<td>9</td>
<td>Culture vessel w/skit and leveling feet's</td>
</tr>
<tr>
<td>10</td>
<td>Piping skid w/ feet's</td>
</tr>
<tr>
<td>11</td>
<td>PV-Box w/ electrical and pneumatic components</td>
</tr>
<tr>
<td>11a</td>
<td>PV-Box extension</td>
</tr>
<tr>
<td>12</td>
<td>Buffer fluid vessel for DMS</td>
</tr>
<tr>
<td>13</td>
<td>Control box lid lifting device</td>
</tr>
</tbody>
</table>
BIOSTAT® D-DCU
Gas Inlet

Sparger aeration
• Stainless steel filter housing
• Bypass line if no Overlay line is installed
• Option: WIT ready filter housing

Overlay aeration (Cell culture)
• Stainless steel filter housing
• Option: WIT ready filter housing
BIOSTAT® D-DCU
Exhaust

Exhaust filter, basic (10-30L only)
• Stainless steel filter housing directly mounted on Exhaust cooler
• High foam sensor included

Exhaust filter line (10-200L)
Single filter line
or
Dual parallel filter line for in process sterilization
Stainless steel filter housing
High foam sensor included
Option: Exhaust heater
Option: WIT ready filter housing
Exhaust Cooler (10–30L)
• Mounted on culture vessel lid
• Shell and tube heat exchanger

Exhaust Cooler (50–200L)
• Mounted in piping skid
• Shell and tube heat exchanger

Pressure control valve
• Mounted in piping skid
Culture vessel

- Vessel with bottom agitation
- Working volume 10, 20, 30, 50, 100, 200L
- Aspect ratio H : D (total): 2:1 or 3:1
- Jacketed stainless steel vessel with torospherical bottom
- Longitudinal viewing window
- Vessel fabrication: PED or ASME or China licence
- Material
  - Product contact: stainless steel AISI 316L, EPDM, borosilicate glass others: AISI 304
  - Surface: internal: Ra [3:1 | 2:1] <= 0.8 | 0.4 µm, electropolished
**BIOSTAT® D-DCU Volume Overview**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10-2</td>
<td>10-3</td>
<td>4.5 - 10</td>
</tr>
<tr>
<td>20-2</td>
<td>20-3</td>
<td>5.5 - 20</td>
</tr>
<tr>
<td>30-2</td>
<td>30-3</td>
<td>6.5 - 30</td>
</tr>
<tr>
<td>50-2</td>
<td>50-3</td>
<td>13 – 50</td>
</tr>
<tr>
<td>100-2</td>
<td>100-3</td>
<td>24 – 100</td>
</tr>
<tr>
<td>200-2</td>
<td>200-3</td>
<td>47 – 200</td>
</tr>
</tbody>
</table>
# BIOSTAT® D-DCU
## Culture vessel port overview

<table>
<thead>
<tr>
<th>Description</th>
<th>Vessel</th>
<th>10 L</th>
<th>20 L</th>
<th>30 L</th>
<th>50 L</th>
<th>100 L</th>
<th>200 L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lid</td>
<td></td>
<td>1 x sight glass for illumination</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>1 x port for CIP - connection</td>
<td>1 x port for Exhaust</td>
<td>1 x port for CIP - connection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x port for Exhaust</td>
<td>9 x 19 mm port</td>
<td>9 x 19 mm port</td>
<td>1 x port for Exhaust</td>
<td>8 x 19 mm port</td>
<td>3 x lifting eyes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x sight glass for illumination</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>8 x 19 mm port</td>
<td>3 x lifting eyes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x sight glass for illumination</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>8 x 19 mm port</td>
<td>3 x lifting eyes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x sight glass for illumination</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>1 x port for Exhaust</td>
<td>8 x 19 mm port</td>
<td>3 x lifting eyes</td>
</tr>
<tr>
<td>Upper side ports</td>
<td>1 x Sparger aeration</td>
<td>4 x 25 mm port</td>
<td>1 x Sparger aeration</td>
<td>4 x 25 mm port</td>
<td>1 x Sparger aeration</td>
<td>4 x 25 mm port</td>
<td>1 x Sparger aeration</td>
</tr>
<tr>
<td></td>
<td>1 x Overlay aeration / Bypass Sparger</td>
<td>4 x 25 mm port</td>
<td>1 x Overlay aeration / Bypass sparger</td>
<td>4 x 25 mm port</td>
<td>1 x Overlay aeration / Bypass sparger</td>
<td>4 x 25 mm port</td>
<td>1 x Overlay aeration / Bypass sparger</td>
</tr>
<tr>
<td></td>
<td>1 x port for rupture disc / safety valve</td>
<td>4 x 25 mm port</td>
<td>1 x port for rupture disc / safety valve</td>
<td>4 x 25 mm port</td>
<td>1 x port for rupture disc / safety valve</td>
<td>4 x 25 mm port</td>
<td>1 x port for rupture disc / safety valve</td>
</tr>
<tr>
<td></td>
<td>1 x rectangular sight glass</td>
<td>4 x 25 mm port</td>
<td>1 x rectangular sight glass</td>
<td>4 x 25 mm port</td>
<td>1 x rectangular sight glass</td>
<td>4 x 25 mm port</td>
<td>1 x rectangular sight glass</td>
</tr>
<tr>
<td>Lower side ports</td>
<td>1 x sanitary TC 50.5 port</td>
<td>5 x 25 mm port</td>
<td>1 x sanitary TC 50.5 port</td>
<td>5 x 25 mm port</td>
<td>1 x sanitary TC 50.5 port</td>
<td>5 x 25 mm port</td>
<td>1 x sanitary TC 50.5 port</td>
</tr>
<tr>
<td></td>
<td>1 x port for temperature sensor</td>
<td>5 x 25 mm port</td>
<td>1 x port for temperature sensor</td>
<td>5 x 25 mm port</td>
<td>1 x port for temperature sensor</td>
<td>5 x 25 mm port</td>
<td>1 x port for temperature sensor</td>
</tr>
<tr>
<td>Bottom</td>
<td>1 x flange for agitator</td>
<td>1 x flange for agitator</td>
<td>1 x flange for agitator</td>
<td>1 x flange for agitator</td>
<td>1 x flange for agitator</td>
<td>1 x flange for agitator</td>
<td>1 x flange for agitator</td>
</tr>
<tr>
<td></td>
<td>1 x Harvest / Drain valve</td>
<td>1 x Harvest / Drain valve</td>
<td>1 x Harvest / Drain valve</td>
<td>1 x Harvest / Drain valve</td>
<td>1 x Harvest / Drain valve</td>
<td>1 x Harvest / Drain valve</td>
<td>1 x Harvest / Drain valve</td>
</tr>
</tbody>
</table>
### BIOSTAT® D-DCU

Scalability via geometrical similarity

<table>
<thead>
<tr>
<th>Scale</th>
<th>10-2</th>
<th>20-2</th>
<th>30-2</th>
<th>50-2</th>
<th>100-2</th>
<th>200-2</th>
<th>10-3</th>
<th>20-3</th>
<th>30-3</th>
<th>50-3</th>
<th>100-3</th>
<th>200-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total volume [L]</td>
<td>14</td>
<td>29</td>
<td>42</td>
<td>74</td>
<td>152</td>
<td>313</td>
<td>15</td>
<td>31</td>
<td>41</td>
<td>77</td>
<td>152</td>
<td>323</td>
</tr>
<tr>
<td>Working volume [L]</td>
<td>10</td>
<td>20</td>
<td>30</td>
<td>50</td>
<td>100</td>
<td>200</td>
<td>10</td>
<td>20</td>
<td>30</td>
<td>50</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>Min. working volume [L]</td>
<td>3.5</td>
<td>5.5</td>
<td>6.4</td>
<td>13</td>
<td>24</td>
<td>47</td>
<td>2.5</td>
<td>3.5</td>
<td>5.4</td>
<td>13</td>
<td>24</td>
<td>41</td>
</tr>
<tr>
<td>H:D ratio [Total Volume]</td>
<td>2.0</td>
<td>2.0</td>
<td>2.2</td>
<td>2.4</td>
<td>2.2</td>
<td>1.9</td>
<td>2.9</td>
<td>3.0</td>
<td>2.9</td>
<td>3.1</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>H:D ratio [Working Volume]</td>
<td>1.3</td>
<td>1.4</td>
<td>1.6</td>
<td>1.6</td>
<td>1.5</td>
<td>1.3</td>
<td>1.9</td>
<td>1.9</td>
<td>2.1</td>
<td>2.1</td>
<td>2.1</td>
<td>2.1</td>
</tr>
<tr>
<td>Impeller to vessel diameter ratio</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.40</td>
<td>0.40</td>
<td>0.39</td>
<td>0.39</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
<td>0.41</td>
<td>0.40</td>
</tr>
<tr>
<td>Max. impeller tip seed</td>
<td>6.7</td>
<td>6.6</td>
<td>6.6</td>
<td>6.4</td>
<td>6.6</td>
<td>7.0</td>
<td>5.9</td>
<td>6.0</td>
<td>6.0</td>
<td>5.9</td>
<td>5.9</td>
<td>6.0</td>
</tr>
<tr>
<td>Impeller to vessel diameter ratio</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.40</td>
<td>0.40</td>
<td>0.39</td>
<td>0.39</td>
<td>0.40</td>
<td>0.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. impeller tip seed</td>
<td>1.9</td>
<td>2.1</td>
<td>2.0</td>
<td>2.0</td>
<td>2.1</td>
<td>2.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lid lifting device

- Available for vessel sizes from 30 – 200L
- Pneumatic operated
- Swivel and lockable
Agitation shaft sealing

Double mechanical seal w/ buffer fluid system
- For microbial and cell culture application
- Lubricated by pressurized condensate
  - Compressed Air pressurization
    - Option: Low level alarm monitoring
  - Steam pressurization
- Sealing material: SIC/carbon graphite
- Condensate vessel with viewing window

Magnetic drive
- For cell culture application only
- Shaft speed monitoring

Agitator w/ DMS
1 Stirrer shaft
2 Impeller
3 Motor
4 Speed sensor
Agitation motor

- Bottom agitation system
- Brushless DC Servomotor
- Gear and maintenance free
- Easy to clean due to smooth surface
6-blade disk impeller

The 6-blade disk impeller produces a flow which moves radially away from the shaft and has a high energy dissipation density. This impeller breaks up air bubbles effectively and thereby improves oxygen transport in the liquid phase. At the same time, high local shear forces are also generated which can have a negative influence on the growth of shear-stress-sensitive organisms (cell cultures, filament-producing fungi).

Design:
Impeller diameter = 0.4 x inner vessel diameter
3-blade segment impeller

3-blade segment impellers for cell culture applications, especially for shear sensitive cells and microcarrier cultures.

The impeller creates an axial downward flow (upward flow version available as option) and thereby achieves homogenous and thorough mixing of the culture medium while minimizing shearing forces.

Design:
Impeller diameter = 0.5 x inner vessel diameter
BIOSTAT® D-DCU
Aeration Devices

Microbial and Cell Culture application
- Ring sparger for 25 mm upper side port
- Holes from bottom

Cell culture application
- Micro sparger for 25 mm upper side port
- Sintered stainless steel frit 20 µm
**Needle assembly for 19 mm port**

**Product description**
- For installation 19 mm top plate port
- Available as
  - 1-Channel assembly
  - 3-Channel assembly

**Operation:**
1. Sterilization in an autoclave together with the addition bottles
2. Sterilization of the culture vessel with septum/ blind plug assembly
3. Remove septum bind plug and the sterile sleeve of the needle and pierce the septum with the needle
Safety Containment Valve (Sacova)

Product description

- Sterile valve for a 19 mm top plate port
- 1-Channel or 3-Channel assembly available
- For tubing 3,2 x 1,6 mm
- High containment class

Operation:

1. Sterilization in an autoclave together with the addition bottle or connected C-flex tubing using a BioWelder for sterile connection

2. After autoclaving installation in the culture vessel and sterilization together with the culture vessel
**BIOSTAT® D-DCU**
**Addition Devices: 4-Valve Addition Array**

4-Valve Addition Array, auto

**Product description**
- Automatic resterilizable valve array for 25 mm port
- For multiple sterile connections during the process
- Perfect fit for connection of bags using BioWelder
- High containment class

**Operation:**
1. Automatic sterilization independently of culture vessel
2. Manual addition valve to be autoclaved with addition bottle/ bag or TPE tubing
3. After autoclaving connection of addition valve and sterilization by steaming of connection lines

① Manual addition valve  
② Steam valve  
③ Bioreactor valve  
④ Condensate valve  
⑤ Hose barb for feed connection
**BIOSTAT® D-DCU**  
Addition Devices: 4 Valve Addition Array, man

---

**4-Valve Addition Array, man**

**Product description**
- Resterilizable valve array for 25 mm port
- Automatic bioreactor, manual valves for steam, condensate and addition
- For multiple sterile connections during the process
- Perfect fit for connection of bags using BioWelder
- High containment class

**Operation:**

1. Manual sterilization separate to culture vessel
2. Manual addition valve to be autoclaved with addition bottle/ bag or TPE tubing
3. After autoclaving connection of addition valve and sterilization by steaming of connection lines

---

1. Manual addition valve
2. Steam valve
3. Bioreactor valve
4. Condensate valve
5. Hose barb for feed connection
Resterilizable Sampling Valve, Keofit

Product description

- Resterilizable Keofit sampling valve for TC 50.5 sanitary port
- For multiple samplings during the process
- Manual steam valve
- Incl. Sterile sleeve

- Optional: Automatic sterilization via automatic steam valve
BIOSTAT® D-DCU
Containment Sampling

Resterilizable Containment Sampling System

Product description

- Resterilizable Keofit sampling valve for TC 50.5 sanitary port
- For multiple sterile samplings during the process
- Manual steam and condensate valves
- Containment sampling bottle

- **Optional**: Automatic sterilization via automatic steam and condensate valves
BIOSTAT® D-DCU
Single-use Sampling

TAKEONE® Single-use sampling

- Aseptic sampling system
- Ready to use
- NO cleaning, preparation and sterilization
- QUICKSEAL®: aseptic tube sealing system
- Sampling bag sealed & disconnected in seconds
BIOSTAT® D-DCU

Drain Valve

Drain valve

Product description

- Radial sealed with TC connection
- Manual or automatic operated
- Sterile sleeve or Condensate line w/ steam trap
- **Optional:** Automatic sterilization via automatic steam and condensate valves or transfer group

Drain valve (100-200L)
Temperature measurement of condensate lines
- For all relevant condensate lines in sterile area
- Contact temperature sensors
- Monitoring via Control Tower

Contact temperature sensor at addition valve array
BIOSTAT® D–DCU
Transfer Valve Group

Transfer valve group (10–30L)
• Automatic valves for steam and Condensate lines
• Manual transfer valve

Transfer valve group (50–200L)
• Automatic valves for steam and Condensate lines
• Automatic transfer and drain valve
**BIOSTAT® D-DCU**
Cleaning In Place (CIP)

**Cleaning In Place**
For the use of an external CIP system, culture vessel is used as a batching tank

- Available for vessel sizes 10 – 200L
- SIP / CIP header
- Automatic CIP sequence for:
  - Culture vessel
  - Aeration line
  - Exhaust line
  - 4-valve addition array, auto
  - Transfer group
- Draining of all CIP lines with compressed air

- Option: Electronic discrete handshake signals (potential free signals)
  1) "DCU message": CIP request
  2) "CIP message": CIP confirm
  3) "CIP message": CIP run
  4) "DCU message": CIP cycle active
mobile CIP Unit

- One system for all vessel sizes (10L – 200L)
- High & low conductivity measurement
- Pump dry run protection
- Up two integrated dosing stations
- D-DCU communication interface for automated CIP sequence control
BIOSTAT® D-DCU
Supporting Documentation

Supporting Documentation

Pre-order:
• Data sheet
• Arrangement plan
• Reference P&ID

Post-order:
• Reference 3D model for room planning
• Operating manual
• Consumable list
• Qualification package
  - As build P&ID
  - Material certificates
  - Functional specification
  - IQ/OQ protocols
Agenda

- Introduction
- System Overview
- Hybrid solution
Hybrid Solutions

Flexboy® or Flexel® bags can be connected to the BIOSTAT® D-DCU for corrective agent and feed addition to reduce cleaning effort. Together with our media preparation system FlexAct® MP and our cell harvest FlexAct® CH, a completely hybrid upstream process solution can be installed at unprecedented low investment cost and a short timeline.

Drivers for Hybrid Solutions

- Reduced cleaning validation
- Pre-sterilized and pre-assembled storage vessels
- Simplified liquid handling and media preparation
- Convenient liquid transportation of feeds, intermediates etc.
- Lower capital investments
- Accelerated commissioning and qualification
- Cost savings

FlexAct® MP (Media Preparation)

FlexAct® CH (Cell Harvest)
Common stainless steel bioreactor design

- Stainless steel storage vessels for corrective agents and feeds
- SIP / CIP requirements for all vessels
- High Steam / WFI requirements
- High capital investment
Example of a Hybrid Solution
Stainless Steel Bioreactor with Single-Use Bags

Advantages

• Single-use bags for media storage and harvest
• SIP / CIP requirement for bioreactor only
• Low Steam / WFI requirements
• Fully flexible
• Reduced cleaning validation
• Lower capital investment
Example of a Hybrid Solution
How to Connect Single-Use Bags?

Tube welding, the easiest way to connect

Operation
• Autoclave re-usable valve with TPE tubing
• SIP of addition / harvest group after connection of the autoclaved valve
• Connect TPE tubing from bag and valve by welding via e.g. BioWelder®
BIOSTAT® D-DCU
Your Fast Track to a Complete Upstream Solution from Media Prep to Cell Harvest

Flexel®
Liquid storage bag

BioSealer®
TPE tube sealer

Sartoclear®
Depth filter

FlexAct®
MP: Media Preparation
CH: Cell Harvest

BioWelder®
TPE tube welder

Sartopore® 2
Liquid Filter

Flexboy®
Media storage bag

TAKEONE®
Aseptic single-use Sampling
Thank you for your attention