

BIOCELL™ Lab & Pilot Series STEAM IN PLACE BIOREACTORS 10L TO 300L W/V

Innovative Solutions and Support



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The BioLogical Choice™

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BIOCELL™ BIOREACTORS

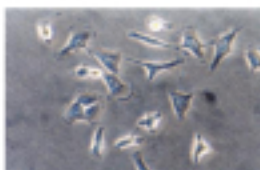
FOR BIOPROCESS SCALE UP AND PRODUCTION RUNS

EXPERIENCE & INNOVATION

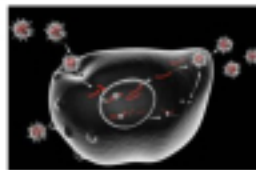
Utilizing its expertise in industrial bioprocesses and automated systems, DCI - BIOLAFITTE offers its BIOCELL™ series, a new generation of Lab & Pilot Steam In Place bioreactors designed for optimization studies, scale-up and production runs in GLP or GMP environments.



These systems represent the best pre-engineered cell culture devices and are suitable for the cultivation of either suspended or attached cells in batch, fed-batch or perfusion mode (with appropriate accessories) .



MAMMALIAN CELL CULTURE



VIRUS AMPLIFICATION

BENEFITS

- Ergonomic, modular and compact systems allowing easy installation and maintenance
- Fully customizable pre-engineered systems designed for R&D, scale-up and productions in GLP or GMP environments
- High thermal transfer performance and minimum shear force via the use of the patented HTPG4™ impeller
- NEPTUNE™ Control system with user friendly / intuitive interface and multiple options
- Micro PLC / PLC – PC based control technology and industrial components ensuring robustness and reliability to the system
- Software developed from non-proprietary platforms complying with GMP requirements (21CFR PART11 and GAMP 5) (*)
- Remote supervision and maintenance of multiple bioreactors via ETHERNET™ network

(*) With the SCADA IFIX or InTouch versions

QUALITY PROGRAM AND QUALIFICATION

- Full system testing and comprehensive FAT
- Rigorous quality program including 100% endoscopic control of process welds with numeric records, full material traceability for product-contact parts and comprehensive tests for problem-free start-up
- Extended test program and documentation package (FS, HDS, SDS, FAT / SAT protocols) designed to support and ease qualification

BIOCELL™ BIOREACTORS

TECHNICAL SPECIFICATIONS

VESSEL, AGITATION & ACCESSORIES

VESSEL

- Jacketed vessel fitted with removable head plate
- Available sizes : 10, 20, 30, 60, 100, 150, 200, 300 w/v - working aspect ratio of 1:1
- Material (product-contact parts): stainless steel grade 1.4404 (316L)
- Finish (product-contact parts): Ra ≤ 20 for vessel (with electro-polishing) and piping
- Maximum operating pressure: 45psig for vessel and jacket

AGITATION

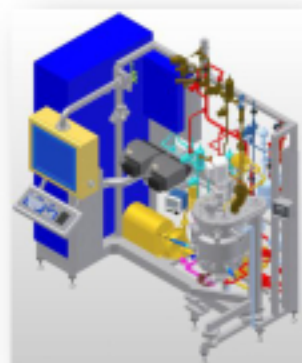
- Bottom or top mounted agitation equipped with one HTPG4™ impeller or equivalent like pitched blade or marine impeller - tip speed : 2 m/s
- Agitation with magnetic coupling

ACCESSORIES

- Round sight glass and illumination lamp
- Sanitary pressure relief valve and pressure gauge
- 3 x sterilizable product lines for inoculation, media loading and sterile additions & disposable connections on request
- 5 x DN25 Ports for standard probes and sensors
- Combined sterilizable harvest and sampling line with flush-mounted diaphragm valve
- Up to four peristaltic pumps including one with adjustable speed for fed-batch or perfusion culture
- Two independent gas supply lines to the overlay (Air and CO₂) and to the sparger (O₂)
- O₂ flow-rate controlled via mass flow controller
- 0.2 µm absolute filters on gas inlet and outlet

Code	Vessel Volume (Working/Total)	Selection
B01	10 L / 20 L	
B02	20 L / 35 L	
B03	30 L / 50 L	
B04	60 L / 90 L	
B05	100 L / 150 L	
B06	150 L / 200 L	
B07	200 L / 280 L	
B08	300 L / 420 L	
Code	Version	Selection
M	Semi-automatic	
A	Full automatic	
Code	Vessel, agitation and accessories options	Selection
00	Oval sight glass to replace round sight glass	
01	Vessel insulation	
03	Independent Spin Filter with magnetic coupling for perfusion	
20	Resterilizable gas filters	
24	Additional resterilizable product addition line	Qty:
25	Resterilizable product transfer line	Qty:
26	CIP devices	
27	Independent resterilizable sampling valve	
30	Nitrogen line with rotameter	
31	Exhaust gas condenser	
32	Double filtration on gas exhaust line	
34	Exhaust gas heater	

Additional equipment (peristaltic pumps, reagent flasks, autoclavable or SIP vessels, scales, CIP units, ...) and customized design for specific applications and biological containment are also available on request.



TEMPERATURE CONTROL

- Cultivation temperature automatically controlled by injection of plant hot or cold water into jacket
- Steam sterilization of empty vessel

Code	Temperature control options	Selection
21	Jacket circulating pump	
22A	Cooling via chilled water circulation in jacket	
22B	Cooling via glycol water heat exchanger ⁽¹⁾	
23A	Heating via steam heat exchanger ⁽¹⁾	
23B	Heating via electric heater ⁽¹⁾	

⁽¹⁾ To be combined with option 21



BIOCELL™ BIOREACTORS

TECHNICAL SPECIFICATIONS

INSTRUMENTATION

- Automatic control of temperature, speed of agitator, pH and pO₂
- O₂ flow rate to the sparger automatically controlled by mass flow meter and air / CO₂ flow rate to the head space controlled via rotameters and automatic valves

Code	Instrumentation Options	Selection
40	Air mass flow controller in replacement of the rotameter	
41	Automatic control of the head space pressure	
43	Foam level control	
44	Vessel low level switch	
45A	Vessel weight measurement (Load Cells)	
45B	Continuous level measurement	
46	Temperature measurement on drain lines	Qty:
47	Feed back control of valve position	Qty:
48	Feed back control of speed	
49	Printer	
50	Control of nutrient flow rate	
51	Optical density measurement	
52	O ₂ , CO ₂ exhaust gas analyzer	



NEPTUNE CONTROL SYSTEM

HARDWARE CONFIGURATION

- Micro-PLC / PC based control with a wide choice of Human Machine Interfaces: laptop or desktop PC as standard or optional Industrial Touch Screen Panel
- Up to 32 configurable control loops for a wide range of process parameters including temperature, pH, Redox, speed control, pO₂, foam, gas flow rates, weight or level, OD, pO₂ / pCO₂ on gas exhaust
- Control types include : PID, digital on/off and others – cascade mode for advanced control strategies

SOFTWARE CONFIGURATION

"Advanced" Version

- Customized User Access module complying with 21CFR PART11 (*)
- Synoptic overview presenting all on-line measured values, actuator status, phase running, alarms
- Parameter Editing module allowing operator for adjusting set-points, PID settings...
- Audit Trail module (iFIX or In Touch versions) capturing all actions made with the software and providing a query SQL database record of a batch with customised report generation
- Trend module allowing data display in the form of trends or historic graphs
- Profile module for controlling set-points via imported or plotted data

"Expert" Version

- Calculation module providing a means to make automatic calculations (RQ, OUR...) in real-time; calculated values can then be logged or implemented as a new process control variable.
- Strategy module enabling a stepwise, user-interactive and repeatable process definition; typically used for feed control, complex gassing addition, set-point ramps or event based actions.
- Additional features such as secure SCADA Server (networked system), remote supervision and maintenance on request

(*) With the SCADA iFIX or InTouch versions

Code	SCADA Configuration	Selection
60La	NEPTUNE LAB in "Advanced" version	
60Le	NEPTUNE LAB in "Expert" version	
60Fa	NEPTUNE SCADA iFIX in "Advanced" version	
60Fe	NEPTUNE SCADA iFIX in "Expert" version	
60Ta	NEPTUNE SCADA InTouch in "Advanced" version	
60Te	NEPTUNE SCADA InTouch in "Expert" version	



AVAILABLE SIZES AND DIMENSIONS (Without control cabinet)

Nominal working volume	Minimum Working volume	Total volume	Depth	Width	Height	Weight Empty
10 L	5 L	17	950 mm	950 mm	1950 mm	175 kg
20 L	8 L	30 L	950 mm	1000 mm	2200 mm	185 kg
30 L	12 L	40 L	950 mm	1050 mm	2300 mm	200 kg
60 L	24 L	90 L	1300 mm	1500 mm	2550 mm	350 kg
100 L	40 L	150 L	1350 mm	1550 mm	2750 mm	480 kg
150 L	60 L	200 L	1350 mm	1550 mm	3000 mm	520 Kg
200 L	80 L	275 L	1400 mm	1600 mm	3350 mm	550 kg
300 L	120 L	400 L	1450 mm	1750 mm	3900 mm	650 kg