



BIOPRO™ Lab & Pilot Series STEAM IN PLACE FERMENTERS 10L to 300L W/V

Innovative solutions and support

**BioPro
Fermenters**
Scale-up and production
GMP applications



PG's fermentation solution: Affordable modularity

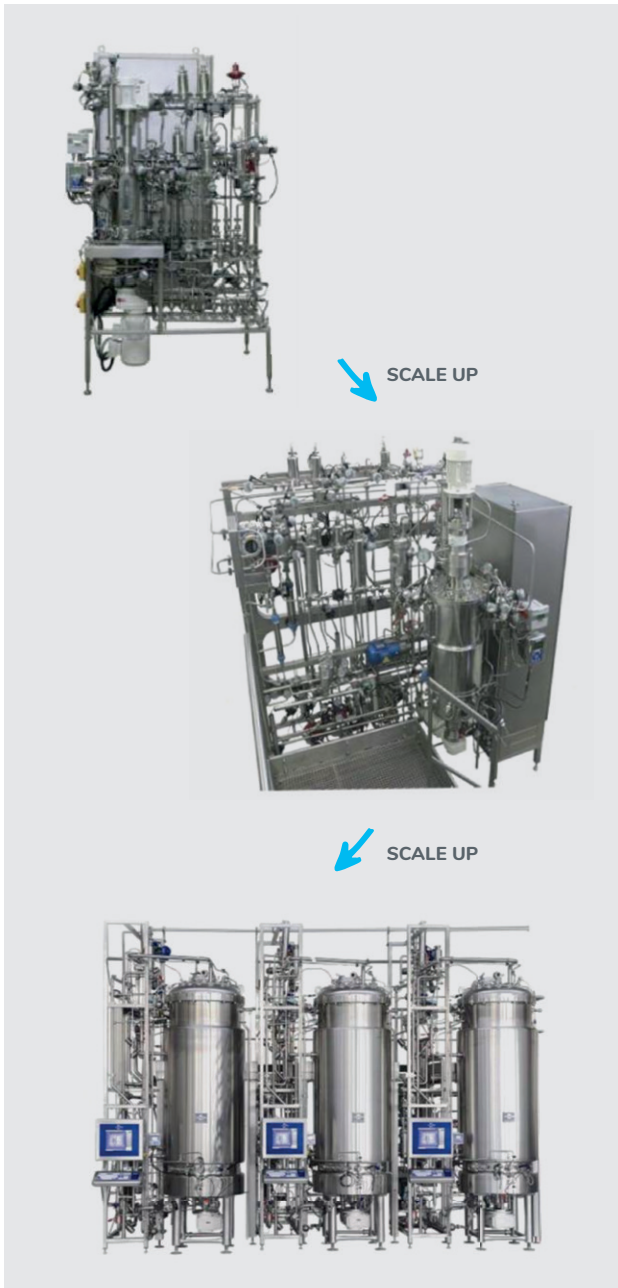


BIOPRO™ FERMENTERS FOR BIOPROCESS SCALE UP AND PRODUCTION RUNS



Experience & innovation

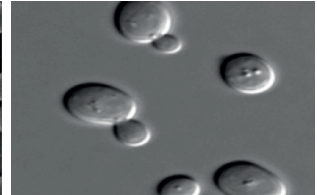
Utilizing its expertise in industrial bioprocesses and automated systems, **PIERRE GUERIN - BIOLAFITTE** introduces its **BioPro™** series, a new generation of Lab & Pilot Steam In Place fermenters designed for optimization studies scale-up and production runs in standard or GLP / GMP environments.



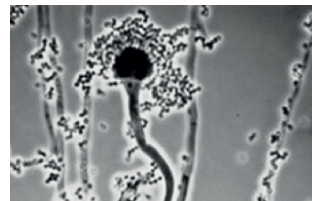
These systems represent the best pre-engineered culture devices and are suitable for many culture types including yeast, bacteria, fungi, in batch, fed-batch or continuous mode (with appropriate accessories).



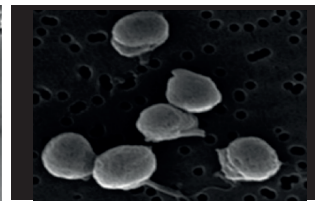
BACTERIAL CULTURE



YEAST CULTURE



MYCELIUM CULTURE



MICRO-ALGAE CULTURE

Benefits

- > Ergonomic, modular and compact systems allowing easy installation and maintenance
- > Fully customizable pre-engineered systems designed for R&D, scale-up and productions available through two different designs to meet all needs: **S Type** for general applications, **G Type** for GLP / GMP validated applications
- > High oxygen and heat transfer performance via the use of the patented **HTPG4™** impeller in combination with **RUSHTON** turbines
- > **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 for 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

Quality program and qualification

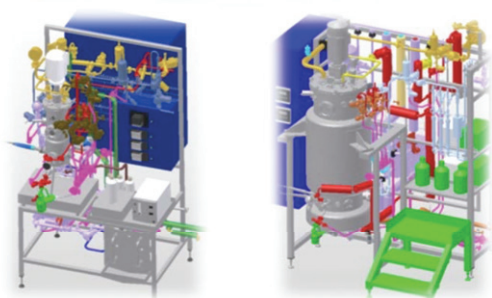
- > Full system testing and comprehensive FAT
- > Rigorous quality program including 100% endoscopic control of process welds and comprehensive tests for problem-free start-up ; G type adds numeric records of welds and full material traceability
- > Extended test program and documentation package (FS,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

BIOPRO™ FERMENTERS TECHNICAL SPECIFICATIONS



Vessel, agitation, accessories & pumps configuration

- > Vessel with a removable flat head plate
- > Working aspect ratio 2:1
- > Double jacket for the automatic control of the culture and media sterilization temperature
- > Material and finish (product-contact parts): stainless steel grade 1.4404 (316L) Ra ≤ 0.8 µm for the vessel and Ra ≤ 1.6 µm (for piping of the type S) Ra ≤ 0.5 µm (with electro-polishing) and piping of the type S
- > Maximum operating pressure: 3 bar g. for vessel and jacket
- > Bottom-mounted agitation
- > Sanitary pressure relief valve and pressure gauge
- > 5xDN25 ports for probes and sensors
- > 0.2 µm absolute filters on gas inlet and outlet
- > Gas supply to the sparger and the headspace



Code	Vessel Volume (Working/Total)	Selection
F01	10L / 17L	
F02	20L / 30L	
F03	30L / 40L	
F04	60L / 100L	
F05	100L / 150L	
F06	150L / 200L	
F07	200L / 275L	
F08	300L / 400L	

Code	Design	Selection
S	Standard	
G	GMP	
M	Semi-automatic	
A	Full automatic	
X1	Rectangular implementation	
X2	Square implementation – (on specific request)	

Code	Temperature control	Selection
23A	Heating via direct steam injection	
23B	Heating via electrical heater and jacket circulating pump	
23C	Heating via steam heat exchanger and jacket circulating pump	
23D	Heating via hot water	
23E	Cooling via chilled water	

Code	Agitation	Selection
02A	Agitation 2 HTPG4 and 1 Rushton – mechanical coupling	
02B	Agitation 2 HTPG4 and 1 Rushton – magnetic coupling	
02C	Agitation 3 Rushton – mechanical coupling	
02D	Agitation 3 Rushton – magnetic coupling	

Code	Accessories	Selection
00A	Round sight glass and illumination lamp	
00B	Oval sight glass and illumination lamp	
01		
03	CIP devices	
	Septum port 4 needles for reagent additions	included
24	A Inoculation tube for sterile addition	
	B Resterilizable combined line Inoculation / Nutrient addition	
	C Inoculation : connexion for a single-use device (Linx, Kleenpack...)	
	D Inoculation : aseptic addition valve (push valve)	
25	B Addition : resterilizable line ⁽¹⁾	Qty :
	C Addition : connexion with single-use device (Linx, Kleenpack...) ⁽¹⁾	Qty :
	D Addition : aseptic addition valve (push valve) ⁽¹⁾	Qty :
	A Sampling via syringe	
27	B Independent resterilizable sampling valve	
	C Novaseptum sampling	
	A Harvesting with bottom sterilisable valve	
28	B Resterilizable harvesting valve	
	C Harvesting with single-use device	
36	Exhaust gas condenser	

Code	Pumps configuration	Selection
41	Alkali integrated fixed speed pump	
42	Anti-foam integrated fixed speed pump	
43	A Nutrient integrated fixed speed pump	
	B Nutrient integrated variable speed pump	
44	Inoculation external variable speed pump	

(1) Maximum 3 lines

BIOPRO™ FERMENTERS TECHNICAL SPECIFICATIONS



Instrumentation and gas configuration

Code	Instrumentation	Selection
	Temperature measurement and control	
	Agitation speed measurement and control	
12	pH measurement and control (pump and bottle not included)	
13	pO ₂ Measurement and control	
14	Detection and control of the foam level (pump and bottle not included)	
16	Optical density measurement	
17	O ₂ / CO ₂ Exhaust gas analyser	
19	Nutrient flow rate control	
15	A Fermenter weight measurement (scale)	
	B Level measurement via differential pressure	
	C Continuous level measurement	
20	A Manual exhaust gas (basic)	
	B Automatic control of the head space pressure	
21	A Temperature measurement on the draining lines of gas outlet and harvest lines	
	B Temperature measurement on the draining lines of product lines	
34	Resterilizable gas filter	
35	Double filtration system on gas outlet line	
37	Exhaust gas heater	



Neptune control system

NEPTUNE™ InTouch software includes the following modules

- > 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 capturing all actions made with the software and providing a query SQL database record for a batch with customized report generation
- > **Trend** module allowing data display in the form of trends or historic graphs
- > **Maintenance** module allowing by-pass



Neptune
PIERRE GUERIN

NEPTUNE InTouch Advanced version

(additional modules to the standard software version)

- > **Strategy** module enabling process to be defined stepwise for process customization and repeatability typically used for feed control, complex gassing addition, set-points ramps or event based actions

NEPTUNE InTouch Expert version

(additional modules to the advanced software version)

- > **Calculation** module providing a means to take automatic calculations (RQ, OTR,...) in real-time. Calculated values can then be logged or implemented as a new process control variable.
- > **Profile** module for controlling set-points via imported or plotted data
- > **Data Offline** module allows definition of offline variables with their specific time stamps and values for a selected batch
- > **Advanced Maintenance** module providing the total function time of each actuated system
- > **Flex Control** module allowing for editing or modifying a controller

Software configuration

Code	Software configuration	Selection
60TA	NEPTUNE SCADA InTouch in <i>Advanced version</i>	
60TE	NEPTUNE SCADA InTouch in <i>Expert version</i>	
-	Remote supervision via Team Viewer	

Available sizes & dimensions (without control cabinet)

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