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F3 – 50/500

PILOT AND SMALL INDUSTRIAL PRODUCTION
SIP BIOREACTORS/FERMENTORS

THE COMPANY

***Bionet is a specialist in bioprocesses engineering.
We provide equipment (Bioreactors, Cross-Flow
Filtration Systems and Cleaning-In-Place Systems)
and advanced technical services***



Our clients are industries and R&D organizations which work with bioprocesses in the chemical, food and pharmaceutical sectors.

Bionet has developed a complete range of bioprocess equipment including series of bioreactors / fermentors, cross-flow filtration systems and "Cleaning-In-Place Systems" (CIPs).

In Bionet, quality is part of our core culture and we work under a certified quality management system, based on ISO 9001:2008.

We work in a full documented engineering environment and provide our equipment with IQ (Installation Qualification), OQ (Operation Qualification) and PQ (Performance Qualification). On demand, the design and qualification may be executed according to cGMP standards.



F SERIES

Bionet F3 models is a unique concept for those seeking for a steam in place (SIP) Bioreactor/ Fermentor of industrial scale and conception, with the quality of a standardized product but with the flexibility of a local vendor.

A system with state-of-the-art technology meant to be the reference in industrial fermentation and cell culture. As all our products it comes with practical conception, and the premium Bionet quality service.

ROSA+ SOFTWARE

ROSA+ is the advanced SW solution created by Bionet to automate bioprocesses equipment and complete bioprocesses lines.

The core module is designed for fermentation and cell culture process control, and it is installed in all Bionet F Series. It is a powerful tool that incorporates all the necessary functions for integrated process control, process qualification and validation, and allows for easy programming of complex recipes with

numerous steps and control loops. ROSA+ has been designed to easily accept and integrate in the process control new instrumentation in the process control.

The application works in a PC environment and allows LAN & VPN connection via Ethernet port.

All software modules are available in 21CFR Part11 compliant version.

F 3

Models

- ▶ Available in five models (F3-50, F3-100, F3-200, F3-300 and F3-500) with working volumes from 50 to 500 litres, and possibility to work with volumes between 30 and 500 litres.
- ▶ cGMP bioreactors and manufacturing under ASME-BPE standards available on demand. It includes CFR 21.11 version of ROSA+ SW.

Gas outlet *1

- ▶ Hygienic design. Outlet contention filter available as an option.
- ▶ Tubular condenser.
- ▶ Available on demand heating unit for outlet filter.

Fermentor *2

- ▶ Vessel and product-contact surfaces made of stainless steel A316L and borosilicate glass.
- ▶ 20+ ports for instrumentation, addition, gas inlet and outlet.

Service valves *3

- ▶ Harvest valve and sampling valve, sterilisable in place by steam supply.

FCU *4

- ▶ Monitoring and additions integrated in Bionet FCU through an industrial PLC (Siemens) and a 12" HMI Panel PC, with ROSA+ control software installed.
- ▶ Several external analog connections available for expansion, accessories and connectivity.
- ▶ Ethernet port with LAN and VPN communication.

Additions *5

- ▶ 3-4 peristaltic wall pumps, 1 with variable speed for fed-batch or continuous fermentation.

Agitator *6

- ▶ Bottom agitation system, servo or electrical motor with gear reduction motor. Broad speed range, adapted depending on the nature of the culture.
- ▶ Available with 3 Rushton impellers (6-blades) or marine turbines (cell culture).
- ▶ Single or double mechanical seal (sterilisable by steam injection).

Control and Monitoring *7

- ▶ Controlled parameters: pH, dissolved O₂, temperature and level (foam). Other parameters (OD, weight, exhaust gas...) can be easily added on demand, even after the equipment delivery and commissioning.

Air supply

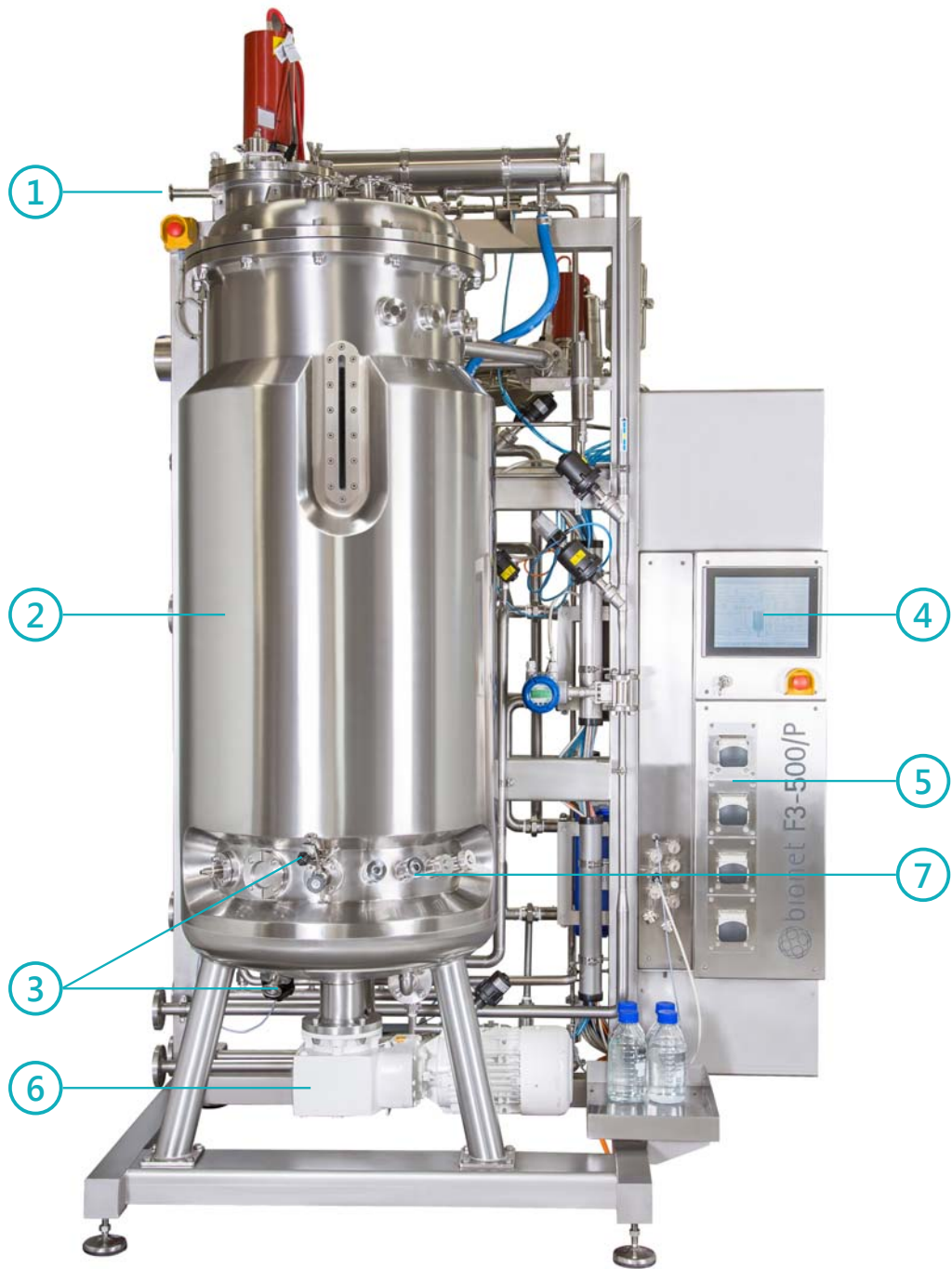
- ▶ Includes flowmeter and automatic flow control, mass flow controller available as an option. Separated from instrument air supply. 0,22 µm sterile filter in air inlet line. Sterilized line and aseptic design.
- ▶ Automatic process pressure control available as an option.

Accessibility and ergonomics

- ▶ Accessibility accessories available for on-top operations (staircase to sight glass and lid lifting crane).
- ▶ Easy access to all services, pipping and electrical panel on the 2D equipment backside.

Safety

- ▶ Aseptic burst disc in fermentor and overpressure relief valve.
- ▶ Main switch on FCU.
- ▶ Emergency button.



TECHNICAL SPECIFICATIONS

MODEL	F3-50	F3-100	F3-200	F3-300	F3-500
Reactor and agitation					
Max. Working volume	50 L	100 L	200 L	300 L	500 L
Vessel design	SIP jacketed stainless steel (A316L) vessel with Kloppler bottom				
Agitator	Lower-mounted agitator with electrical motor and gear reducer				
Seal	Single-mechanical seal (FDA compliant design). Double-mechanical seal and magnetic coupling available as an option.				
Impellers	3 (6-blades) Rushton impellers (M) or Marine Impellers (C)				
No. of Baffles	4				
Materials	Vessel and all product-contact parts made of stainless steel A316L and borosilicate glass, rest of stainless steel A304. EPDM and silicone gaskets. Product-contact surfaces (Ra <0,8 µm) polished. Ra <0.5 µm and/or electropolishing available on demand.				
Isolation	50 mm Rockwool (available as an option)				
Microbiology					
Total volume (M)	75 L	143 L	250 L	446 L	690 L
Working volume % (M)	67	70	70	67	73
Min. Working Volume (M)	17 L	25 L	50 L	65 L	95 L
Total H:D (M)	3:1	3:1	3:1	3:1	3:1
Working H:D (M)	1,8:1	2,3:1	2,3:1	1,9:1	2,0:1
Agitation speed (M)	100 – 700 rpm	100 – 800 rpm	100 – 800 rpm	150 – 500 rpm	150 – 500 rpm
Impeller to vessel internal diameter ratio (M)	0.30-0.35				
Motorpower (M)	2,2 kW	2,2 kW	3 kW	5,5 kW	5,5 kW
Bioreactor height (M)	962 mm	1206 mm	1601 mm	1782 mm	2216 mm
External diameter (M)	325 mm	406 mm	530 mm	610 mm	670 mm
Cellular					
Total volume (C)	75 L	142 L	294 L	426 L	704 L
Working volume % (C)	67	70	68	70	71
Min. Working Volume (C)	20 L	32 L	62 L	77 L	118 L
Total H:D (C)	2:1	2:1	2:1	2:1	2:1
Working H:D (C)	1,2:1	1,5:1	1,5:1	1,3:1	1,3:1
Agitation speed (C)	25 -200 rpm	25 – 200 rpm	25 – 200 rpm	40 – 125 rpm	40 – 125 rpm
Impeller to vessel internal diameter ratio (C)	0,4 – 0,5				
Motorpower (C)	1,5 kW	1,5 kW	2,0 kW	2,2 kW	2,2 kW
Bioreactor height (C)	770 mm	985 mm	1278 mm	1501 mm	1745 mm
External diameter (C)	365 mm	450 mm	600 mm	660 mm	785 mm
Dimensions					
Plant height and footprint (frame included) (mm)	1500(W) x 2197(H) x 810(D)	1500 (W) x 2273(H) x 830(D)	1500 (W) x 2653(H) x 950(D)	1625(W) x 3107 (H) x 1135(D)	1690(W) x 3420(H) x 1210(D)

MODEL	F3-50	F3-100	F3-200	F3-300	F3-500
Ports					
Lid	1 x Exhausting gas condenser (1 ½") 2 x Foam level switches (1 ½") 1 x Spare (1 ½") 1 x Sight glass + projection (DN50) 6 x Additions and probes (1 ½") 1 x Pressure gauge (1 ½")				
Upper side ports	1 x Vertical graduated sight glass 4 x Addition ports (DN30) 1 x Air/steam direct inlet port (NA-CONNECT ¾") 1 x Air/steam inlet via sparger (½") 1 x Burst disc (1 ½")				
Lower side ports	1 x Ingold port dO ₂ probe (DN25) 1 x Ingold port pH probe (DN25) 2 x Spare Ingold ports (DN25) 1 x Sampling device (NA-CONNECT 1 ½") 1 x Spare (NA-CONNECT 2 ½") 1 x Temperature transmitter (NA-CONNECT 1 ½")				
Bottom	1 x SIP diaphragm harvest valve (1") 1 x Agitator (DN180)				
Control and Instrumentation					
Automation	Industrial PLC (Siemens) + Modules E/S. Touch Panel PC12" SVGA 800 x 600				
SW de control	R.O.S.A. +				
FCU	Integrated in frame				
Cover Material	Stainless steel A304 (matte finish)				
Communication	2 x Ethernet ports for LAN and VPN communication for remote control. 1 x USB port for data downloads. 2 x External configurable analog inputs (additional probes) 1 x External configurable analog output (additional dosage pump) 1 x RS485 for communication with external elements.				
Standard sensors	pH, dO ₂ , temperature, foam level				
pH control	Range: 0 – 14 (± 0,01)				
dO ₂ control	Optical sensor. Range: 0 – 100% (±0,1%)				
Foam control	Second foam control level available as an option				
Optional sensors	Optical density/turbidity, exhausting gas, redox, load cell, dissolved CO ₂ , level and on-top pressure.				
Temperature control	Sensor: Range 5-130 °C (± 0,01). Temperature control by recirculation system. Heat exchanger for temperature control consisting of primary circuit with cold water/steam.				
Sterilisation control	Automatic sterilisation control (steam to jacket/direct steam)				
Aeration control	1-2 vvm. Air supply y regulation (valve + flowmeter) Mass-flow controllers (MFCs) available as an option Other gases supply (O ₂ , N ₂ , CO ₂ ...) available as an option				
Pressure control	Manual pressure regulation by proportional valve or needle valves. Valves are automatically adjusted to sterilization and fermentation mode.				
No. of Pumps	3 attached peristaltic addition pumps (Watson Marlow), option to 1 additional attached pump. One external addition pump, for fed-batch and continuous systems, available as an option.				
Pneumatic panel	Integrated in FCU				
Utilities Requirements					
Compressed air supply (Q _{max})	6-7 barg/ 1-2vvm (12 Nm ₃ /h)	6-7 barg/ 1-2vvm (24 Nm ₃ /h)	6-7 barg/ 1-2vvm (48 Nm ₃ /h)	6-7 barg / 1-2vvm (72 Nm ₃ /h)	6-7 barg/ 1-2vvm (120 Nm ₃ /h)
Steam supply	2,5 barg/ 25 Kg/h	2,5 barg/ 50 Kg/h	2,5 barg/ 70 Kg/h	2,5 barg/ 70 Kg/h	2,5 barg/ 180 Kg/h
Independent clean steam line	Available as an option				
Utility cost (M/C)	4,6 kW	5,7 kW	5,7 kW	6,0 kW	6,6 kW
Cooling water; Supply/ return	1-3 bar - 10°C(*) / 1-3 bar - 15°C	1-3 bar - 10°C(*) / 1-3 bar - 15°C	1-3 bar - 10°C(*) / 1-3 bar - 15°C	1-3 bar - 10°C(*) / 1-3 bar - 15°C	1-3 bar - 10°C(*) / 1-3 bar - 15°C

(*) Cooling water supply temperature will determine the minimum controllable temperature within the fermentor (at least 10 °C higher than the cooling water temperature).



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