



F2 – 15/30

SIP PILOT SCALE
BIOREACTORS

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 F2 models are designed for both R&D and small industrial productions due to its high level of automation, control and flexibility on a robust and reliable design and construction.

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 2

Models

- ▶ Available in two models (F2-15 and F2-30) with working volumes of 15 and 30 liters, respectively, and possibility to work with volumes between 6 and 30 liters.
- ▶ Available in self-sterilisation version with integrated steam supply.
- ▶ 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.
- ▶ Heating unit for outlet filter available on demand.

Fermentor *2

- ▶ Vessel and product-contact surfaces made of stainless steel A316L and borosilicate glass.
- ▶ 15+ 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, one with variable speed for fed-batch or continuous fermentation.

Agitator *6

- ▶ Noiseless, top-mounted agitator with brushless servomotor. 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

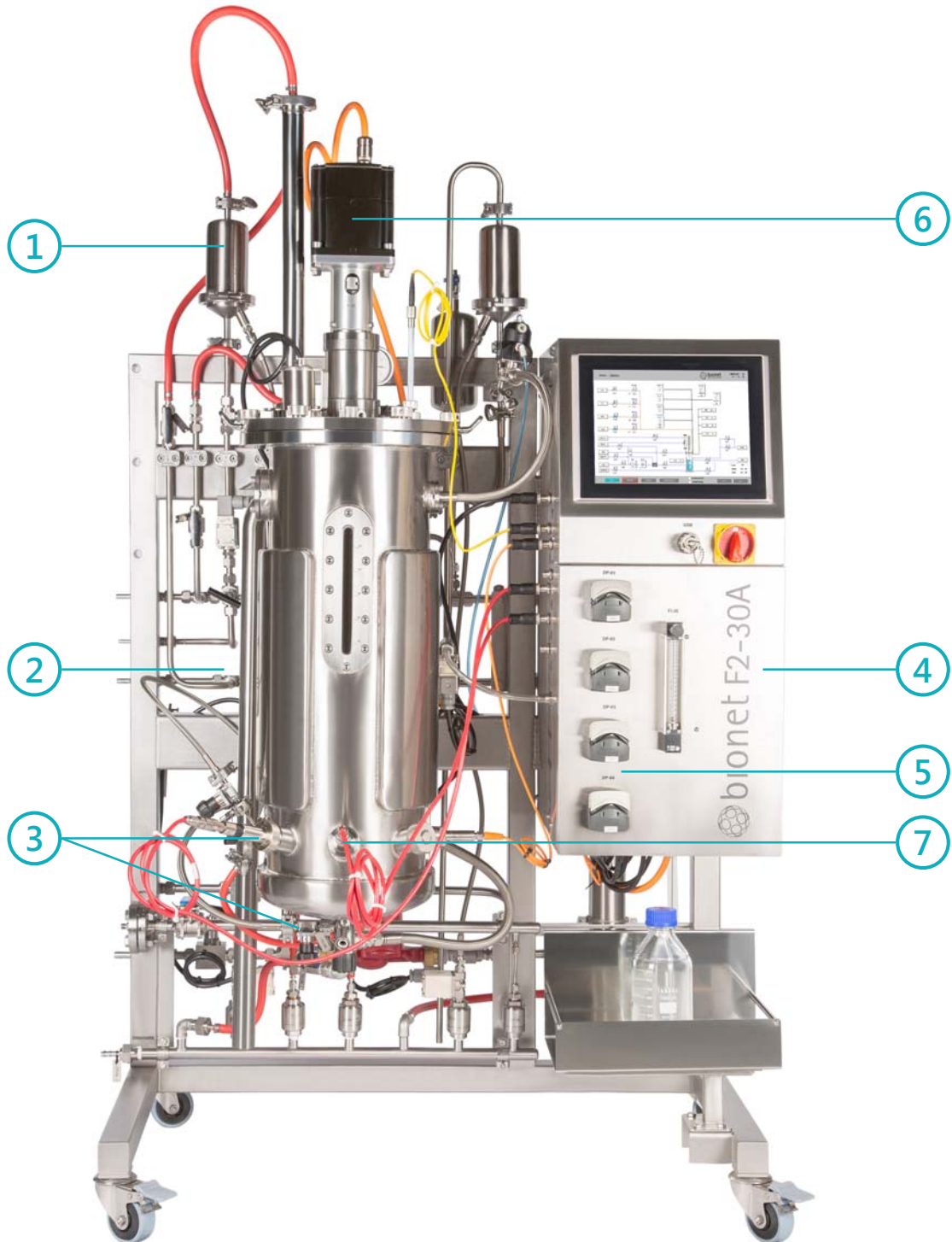
- ▶ Includes flowmeter and automatic flow control, mass flow controller available as an option. 0,22µm sterile filter in air inlet line. Sterilisable line and aseptic design.
- ▶ Automatic process pressure control available as an option.

Accessibility and ergonomics

- ▶ Accessibility accessories available for on-top operations (staircase to sight glass and lid lifting crane).

Safety

- ▶ Aseptic burst disc in fermentor and overpressure relief valve.
- ▶ Main switch.



TECHNICAL SPECIFICATIONS

Model	F2-15	F2-30
Reactor and agitation		
Max. Working volume	15 L	30 L
Vessel design	SIP jacketed stainless steel (A316L) vessel with Kloppler bottom	
Agitator	Top-mounted agitator with servomotor.	
Seal	Single-mechanical seal (FDA compliant design). Double-mechanical seal available as an option.	
Impellers	3 (6-blades) Rushton impellers (M) or Marine Impellers (C)	
N° 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.	
Microbiology		
Total volume (M)	22 L	44 L
Working volume % (M)	68	70
Min. Working Volume (M)	6 L	12 L
Total H:D (M)	3:1	3:1
Working H:D (M)	2,1:1	2,1:1
Agitation speed (M)	150 – 1200 rpm	
Impeller to vessel internal diameter ratio (M)	0,33	
Motorpower (M)	0,6 kW	1,1 kW
Bioreactor height (M)	641 mm	801 mm
External diameter (M)	219 mm	273 mm
Cellular		
Total volume (C)	22 L	43 L
Working volume % (C)	69	70
Min. Working Volume (C)	7 L	10,5 L
Total H:D (C)	2:1	2:1
Working H:D (C)	1,2:1	1,5:1
Agitation speed (C)	10 -400 rpm	10 -400 rpm
Impeller to vessel internal diameter ratio (C)	0,4 – 0,5	
Motorpower (C)	0,37 kW	0,6 kW
Bioreactor height (C)	505 mm	647 mm
External diameter (C)	245 mm	303 mm
Dimensions		
Plant height and footprint (frame included) (mm)	1100(W) x 1962(H) x 700(D)	1100(W) x 1962(H) x 700(D)

Model	F2-15	F2-30
Ports		
Lid	1 x Exhausting gas condenser (1 ½") 1 x Manhole with sight glass + projection (ø _{ext} : 73 mm) 5 x Additions and probes (D19) 1 x Pressure gauge (1") 1 x Agitation (ø _{ext} : 42,1 mm)	
Upper side ports	1 x Vertical graduated sight glass 1 x Air/Steam direct inlet (ø _{ext} : 55 mm) 1 x Air/Steam inlet via sparger (ø _{ext} : 54 mm) 2 x Spare (1 ½")	
Lower side ports	3 x Ingold port (G 1 ¼") (O ₂ measurement/control + pH + spare) 1 x temperature measurement/control port (G ½") 1 x Sampling port (NA-CONNECT ½")	
Bottom	1 x SIP diaphragm harvest valve	
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 peristaltic addition wall pumps (Watson Marlow), option to 1 additional wall pump. 1 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 (3,6 Nm ³ /h)	6-7 barg/ 1-2vvm (7,2 Nm ³ /h)
Steam supply	2,5 barg/ 25 Kg/h Self-sterilising Option: Version with self-sterilization kit that allows working without external steam supply	2,5 barg/ 25 Kg/h Self-sterilising Option: Version with self-sterilization kit that allows working without external steam supply
Utility cost (M)	4,6 kW (10,9 kW if self-sterilising)	4,6 kW (10,9 kW if self-sterilising)
Utility cost (C)	4,4 kW (10,7 kW if self-sterilising)	3,9 kW (10,2 kW if self-sterilising)
Cooling water; Supply/ return	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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