bionet
ENGINEERING

FS – 1000/3000

SIP BIOREACTORS/FERMENTORS FOR
INDUSTRIAL PROCESSES

AENOR
Empresa Registrada
UNE-EN ISO 9001

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

The BIONET FS models are thought to fill a market gap so far unresolved: medium and large volume fermentors which being competitive with local suppliers, provide the great advantages of carefully engineered equipment and mass-manufactured.

Bioreactors entirely built at the workshop, with a self-supporting frame, assembled and fully tested prior to shipment to the customer. After the FATs (Factory Acceptance Test), the bioreactors are stripped out to be assembled in its final location.

It is a unique "plug and play" concept for large bioreactors. A safe and quick alternative to reduce risks in projects, which were hitherto performed as unique with the limitations and risks that entails.

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 S

Models

- Available in three models (FS-1000, FS-2000 and FS-3000) with max. working volumes from 1000 to 3000 liters, and possibility to work with volumes between 150 and 3000 liters.
- 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.
- Self-draining 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.
- 25+ 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

- By pressurization from storage tanks of acid/base, antifoam and nutrients. Addition controlled by pneumatic valves integrated in control SW.

Agitator *5

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

Control and Monitoring *6

- Controlled parameters: pH, dissolved O_2, 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

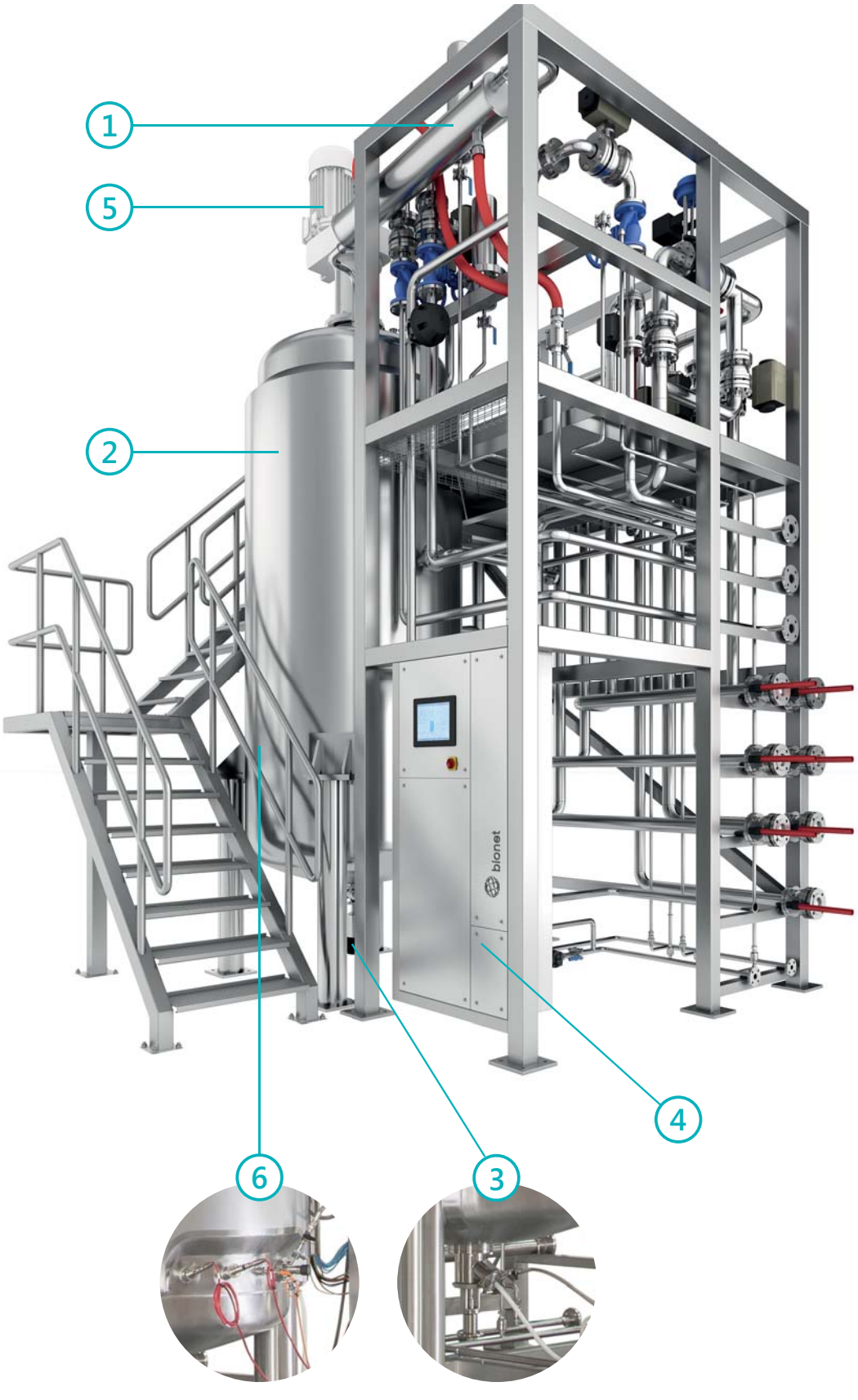
- Includes flowmeter and automatic flow control, mass flow controller available as an option. Separated from instrument air supply. 0,22 µm sterile filter in air inlet line. Sterilized line and aseptic design.
- Automatic process pressure control available as an option.

Accessibility and ergonomics

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

Safety

- Aseptic burst disc in fermentor and pressure release valve.
- Main switch on FCU.
- Emergency button.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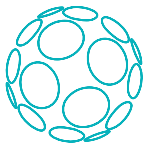
TECHNICAL SPECIFICATIONS

MODEL	FS-1000	FS-2000	FS-3000
Reactor and agitation			
Max. Working volume	1000 L	2000 L	3000 L
Vessel design	SIP jacketed stainless steel (A316L) vessel with Kloppler bottom		
Agitator	Top-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)	1342 L	2650 L	3700 L
Working volume % (M)	75	75	80,1
Min. Working Volume (M)	150 L	270 L	450 L
Total H:D (M)	3:1	3:1	3:1
Working H:D (M)	1,7:1	2,1:1	2,5:1
Agitation speed (M)	20 - 300 rpm	20 – 250 rpm	20 - 200 rpm
Impeller to vessel internal diameter ratio (M)	0.30-0.35		
Motorpower (M)	5,5 kW	7,4 kW	7,4 kW
Bioreactor height (M)	2590 mm	3480 mm	3640 mm
External diameter (M)	880 mm	1100 mm	1250 mm
Cellular			
Total volume (C)	1420 L	2727 L	4290 L
Working volume % (C)	70	73	70
Min. Working Volume (C)	220 L	335 L	496
Total H:D (C)	2:1	2:1	2:1
Working H:D (C)	1,3	1,3	1,3
Agitation speed (C)	20 -250 rpm	20 – 200 rpm	20 – 200 rpm
Impeller to vessel internal diameter ratio (C)	0,4 – 0,5		
Motorpower (C)	2,2 kW	5,5 kW	5,5 kW
Bioreactor height (C)	1852 mm	2820 mm	3247 mm
External diameter (C)	1010 mm	1200 mm	1400 mm
Dimensions			
Plant height and footprint (frame included) (mm)	2155(W) x 4240(H) x 1950(D)	2575(W) x 5128(H) x 2320(D)	2725(W) x 5286(H) x 2520(D)

MODEL	FS-1000	FS-2000	FS-3000
Ports			
Top	1 x Manhole with sight glass (DN50) 4 x Additions (DN19) on multipurpose lid (DN125) 1 x Foam level switch (½") 1 x Exhaust (2 ½") 1 x Pressure indicator (1 ½") 1 x CIP (1 ½") 1 x Burst disc (1 ½") 1 x Sight glass with projection (DN80) 1 x Agitator (DN250)		
Upper side ports	1 x Air/steam inlet via sparger (NA-CONNECT, 2") 1 x Air/steam direct inlet (NA-CONNECT, ½")		
Lower side ports	1 x pH probe (Ingold, DN25) 1 x dO_2 probe (Ingold, DN25) 1 x Temperature transmitter (G ¾") 1 x Sampling device (NA-CONNECT, 1 ½") 1 x CIP (1 ½")		
Bottom	1 x SIP diaphragm harvest valve (2")		
Control and Instrumentation			
Automation	Industrial PLC (Siemens) + Modules E/S. Touch Panel PC12" SVGA 800 x 600		
SW 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 ºC (± 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 vvms. Air supply y regulation (valve + flowmeter) Mass-flow controllers (MFCs) available as an option Other gases supply (O_2, N_2, CO_2...) available on demand.		
Pressure control	Manual pressure regulation by proportional valve or needle valves. Valves are automatically adjusted to sterilization and fermentation mode.		
No. of Pumps	To define according to customer URs. Autoclavable peristaltic wall or external pumps (WM) available to be installed. As well as membrane pumps with autoclavable stainless steel pipe (manual or auto mode) from sterilisable tanks or bottles.		
Pneumatic panel	Integrated in FCU		
Utilities Requirements			
Compressed air supply (Q_{max})	2 barg | 1-2vvm (240 Nm³/h)	2 barg | 1-2vvm (480 Nm³/h)	2 barg | 1-2vvm (720 Nm³/h)
Steam supply	2,5 barg | 300 Kg/h	2,5 barg | 375 Kg/h	2,5 barg | 450 Kg/h
Utility cost (M/C)	6,6 kW | 3,3 kW	12 kW | 10,1 kW	12 kW | 10,1 kW
Cooling water; Supply/ return	1-3 bar - 10ºC(*) / 1-3 bar - 15ºC	1-3 bar - 10ºC(*) / 1-3 bar - 15ºC	1-3 bar - 10ºC(*) / 1-3 bar - 15ºC

(*) 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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