

# Bioprocess Lab and Pilot Equipment

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F0

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F1

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**F2**



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F3

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M1

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M2

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MARTA & ROSITA

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# F2

## Bioprocess Lab and Pilot Equipment

### VALUE PROPOSITION

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The models in the F2 series are the perfect solution for all those seeking for their first Steam In Place (SIP) stainless steel bioreactor/ fermenter for the scaling up of their bioprocesses and for small production applications. They are available in working volumes from 10 to 30 L.

With a professional design and construction, which makes the F2 the reference in the market, it incorporates many extraordinary details to offer a user-friendly experience, ready to be easily integrated into your facilities.



## KEY BENEFITS

### ADVANCED PROCESS CONTROL

Providing the possibility to add a complete range of instrumentation and actuators, and allowing all kinds of associated control strategies helps you to better understand and improve your processes.

- Example of instruments which can be added beyond the standard configuration are: Pressure, Optical Density, Viable Cells, Dissolved CO<sub>2</sub>, Exhaust gas composition, Redox, Weight and many others.

- Most of these instruments have a corresponding MARTA SW module. These specific SW modules allows the user to select parameter as part of your control strategies and gives additional calculated information (e.g. OTR or OUR) in real time.



### INTEGRATED CIP & SIP

The F2 can be delivered with integrated utilities (SIP and CIP) to help you to start your journey SIP Bioreactors in an easy way and with a minimal investment.

- All in the same frame, with no extra-footprint. All controlled from our control SW MARTA with specific screens for complete control and programming of your Sterilization and Cleaning In Place Cycle.

### EXPANDABLE

- As in all BIONET products, the F2 can be adapted to the specific needs of your scale-up and small production activities, including:
  - Customisable gas module with up to 4 gas inlets and gas mixing combinations (air, O<sub>2</sub>, N<sub>2</sub>, CO<sub>2</sub>).
  - Option to add another 3 dosage peristaltic pump per vessel, for nutrient addition in fed-batch, continuous or perfusion mode configurations.

## GMP COMPLIANT

As all BIONET equipment and projects the F2 can be designed, built and qualified under GMP guidelines to allow the validation of your processes.

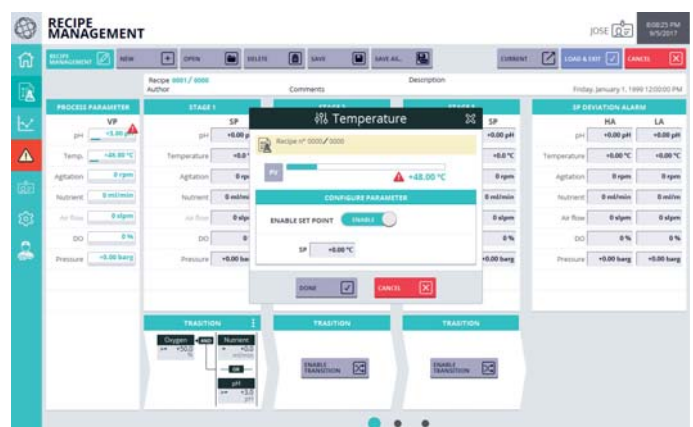
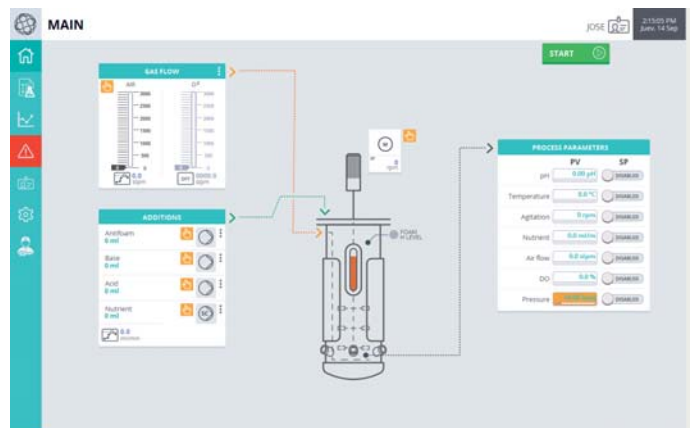
- Our GMP approach is structured so it can be adapted to your specific project and regulatory needs. The upgrade from a standard unit to a GMP one will affect many issues on the design and construction: Technologies, Calibrations, Documentation, Qualification and SW (including ER under CFR 21 c 11).

# DQ, IQ, OQ.

## AUTOMATION

MARTA is the Automation SW which comes installed in the F2 units. In this model has off-the-shelf solutions for Cell Culture, Fermentation which can be expanded with additional modules for local SIP and CIP, new instrumentation or advanced gassing or dosing control.

- F2 can be also supplied with ROSA, our entry level SW for non GMP or entry-level users.



	F2 MB	F2 CC		F2 MB	F2 CC
<b>GENERAL</b>			<b>TEMPERATURE CONTROL</b>		
Material	316L SS in surfaces in contact with product. 304 SS in frame and electrical cabinet. Borosilicate in sight glass. All gaskets FDA compliant.		Cooling	Secondary circuit from an external chilled water source to heat exchanger in main circuit	Secondary circuit from an external chilled water source to heat exchanger in main circuit
Skid footprint (W x H x D)	1200 x 1993 x 740	1200 x 1993 x 740	Heating	Electrical resistance in water circuit	Electrical resistance in water circuit
<b>VESSEL &amp; PORTS</b>			Autonomous (no need of external steam supply)	○	○
Working volumes available (L)	15, 30	15, 30	<b>INSTRUMENTATION</b>		
Vessel total volume (L)	22, 44	22, 43	Basic instrumentation package	pH, DO, temperature, level	pH, DO, temperature, level
Vessel design	Top flat lid, Klöpper bottom. Jacketed including bottom.	Top flat lid, Klöpper bottom. Jacketed including bottom.	Instrumentation available as add-on	Optical Density, Redox potential, Exhaust gas composition, Conductivity, Volume and Weight	Optical Density, Redox potential, Exhaust gas composition, Conductivity, Viable cells, Volume and Weight
Minimum working volume (L)	6 (15L) 12 (30L)	7 (15L) 10.5 (30L)	<b>EXPANSION POSSIBILITIES</b>		
Total H:D	3:1	2:1	Advanced Gas Module (Air, O <sub>2</sub> , CO <sub>2</sub> , N <sub>2</sub> ) in sparger and overlay	○	●
Working H:D	2.1:1	1.5:1	Variable speed pump for dosing	○	○
<b>AGITATION</b>			Continuous process module	○	○
Agitator	Top mounted Standard: Single mechanical seal *Optional: Double mechanical seal	Top mounted Standard: Single mechanical seal *Optional: Double mechanical seal or magnetic coupling	Perfusion module	○	○
Impellers	Standard: 3x Rushton Optional: Marine/ Pitched blade; or customised	Standard: 1x Marine Optional: customised (upon demand)	Scales (for precision in additions, sampling, harvesting, continuous processing and perfusion)	○	○
Speed (rpm)	30-1200	10-400	CIP (Integrated Cleaning in Place) module	○	○
Motorpower	0.6 kW (15L) 1.1 kW (30L)	0.37 kW (15L) 0.6 kW (30L)	Additional sensors (and associated control loops)	○ (e.g. for automatic pressure control)	○ (e.g. for automatic pressure control)
<b>GASSING MODULE</b>			Other customized modules	○	○
Gas lines	Standard: Air Optional: conversion of existing gas or addition of extra gas lines	Standard: Advanced gassing control unit with Air, O <sub>2</sub> , N <sub>2</sub> and CO <sub>2</sub>	<b>AVAILABLE MECHANICAL ACCESSORIES</b>		
Gas inlet to vessel	Standard: Sparger Optional: Overlay	Standard: Sparger and Overlay	Sterile Addition Ports (SIP); Crane; Stairs; Spray ball; Range of Dip Tubes; Several types of turbines; Additional Port Plugs		
Gas flow control and gas mixture	Standard: manual via rotameters Optional: automatic MFCs	Standard: automatic via MFCs	<b>GMP</b>		
Gas flows	Air: 1.5 VVM. O <sub>2</sub> : 0.5 VVM All flows can be modified on demand	Air: 0.5 VVM O <sub>2</sub> : 0.05-0.1 VVM CO <sub>2</sub> : 0.05-0.2 VVM N <sub>2</sub> : 0.05-0.2 VVM All flows can be modified on demand	○		
0.22 µm filter in gas inlet	●	●	<b>AUTOMATION</b>		
Condenser for exhaust gas	●	●	Installed SW	MARTA or ROSA	MARTA or ROSA
0.22 µm filter at exhaust gas	○	○	HMI	Integrated touch panel PC 12"	Integrated touch panel PC 12"
<b>DOSAGE MODULE</b>			Remote access	Additional Ethernet port, for local remote access from any user within the LAN and external remote access from outside the client's site via a safe VPN tunnel	Additional Ethernet port, for local remote access from any user within the LAN and external remote access from outside the client's site via a safe VPN tunnel
Pumps	Standard: 3x fixed speed Optional: extra variable speed pumps (3) for a total of 6	Standard: 3x fixed speed Optional: extra variable speed pumps (3) for a total of 6	<b>UTILITY REQUIREMENTS</b>		
			Chilled water	1,000 kg/h@1-3 bar 8-12° C	1,000 kg/h@1-3 bar 8-12° C
			Compressed air	3.6-7.2 Nm <sup>3</sup> /h@6-7 barg	0.5-1.0 Nm <sup>3</sup> /h@6-7 barg
			Steam	25 kg/h@2.5 barg	25 kg/h@2.5 barg
			Electricity	4.8 kW (10.8 kW autonomous)	4.8 kW (10.8 kW autonomous)

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