

IN SITU STERILIZABLE BIOREACTORS



Bio Sip

In situ Sterilizable Bioreactors Kbiotech team with over 20 years experience in sterile process engineering and bioprocess technologies has realised a complete range of laboratory and pilot SIP in situ sterilizable bioreactors and fermenters. Kbiotech offer pre-assembled SIP bioreactors packages or custom made solutions based on detailed requirements.

Culture vessels are available in bacteriological or cell cultivation configurations in the standard volumes from 3 to 5000 litres , or customized volumes up to 50 cubic meters and more on request.

High Flexibility and Reliability via PLC automation and BIOFLEX SCADA software



Modularity and upgrades at any time thanks to our new Modular concept design



Complete documentation. IOQ, DQ and components traceability for GLP and cGMP

Service and Maintenance with a worldwide network



KBIOTECH SOLUTION FULL CONTROL & FLEXIBILITY

Our laboratory and pilot SIP bioreactors are designed to guarantee better performances and improve process conditions like scaling up or scaling down, mixing and oxygen transfer, heating/cooling thermal transfer, sterility and cleaning procedures to optimize manufacturing time and costs saving.

BioSip automation & software Are based on leading supplier PLC's that runs under an advanced intuitive operating system. Software comprises a PLC with local visualization platform, HMI human interface touch screen and custom made configuration.

BioSip automated platforms guarantee the best performances, reliability, long term service and spare parts availability unless proprietary systems. The selection of trusted hardware components united with our background in fermentation and cell culture implemented into the BIO-SIP Controller Software ends up into a unique advanced SIP bioreactors solution.

BioSip Controllers series are powered through a UPS device protecting it from interference, overvoltage and power cuts. All units are provided with an automated re-start sequence in case of power supply failures. Hardware components are located into a classified waterproof cabinet IP55/65 certified.

BioSip Controller architecture can hold and simultaneously manage up to 2 or more Lab and Pilot bioreactors. Automation design and functionality allow to interchange vessel's size without modifying PLC or Software configuration.

Advanced technology reflect also the use of field-bus based I/O modules for accurate and fast data management and to allow easy maintenance and to be ready for any expansion later on. Each system can be upgraded and replaced at any time without any limitation.

Reduce lab space and energy consumption.

Easy to use with a simpler User Interface.

Full material traceability and certifications.

Various Accessories available.

Maximum flexibility with wide choose of Hardware solutions.

Simultaneous control and regulation:

- 2 x pH
- 2 x pO2
- 10 or more temperature
- 2 x level and foam
- 2 x stirrer speed
- 2 x pressure
- up to 8 x variable speed or fix speed peristaltic pumps
- up to 8 or more MFC's or rotameters
- up to 4 load cells
- 8 or more balances

Extra inputs:

- biomass monitors
- · optical density
- gas analyzer
- pCO2
- methanol analyzer
- automated samplers and others.

Chosen of leading PLC: Siemens, National Instruments, Allen Bradley, Delta V.

Chosen of Communication device: Canopen, Interbus, Profibus, DeviceNet, ControlNet, ModBus, RS232/485, Ethernet, USB

BioSip HUMAN INTERFACE TOUCHSCREEN

The **Bio**Sip HMI-PC is a unique interface that allow full local control of the bioreactor. Large Touch-screens available in 15", 19", 21".

Functionalities:

- Full or empty automated sterilization cycles in one touch
- Preparation phases
- Pre-Inoculation set-up
- Inoculation assistance procedure
- Fermentation or Cell cultivation process start-up guided procedures
- Easy configuration of process parameters,
- P.I.D. settings,
- Probes and pumps calibration
- Dose monitoring for pumps and MFC's
- Up to 4 level of alarms
- Up to 4 password access
- Sequences programming
- Batches and feeding profiles formulations
- Cascade controls
 and exponential equations
- Online data recording
 with memory card
- Data download via USB/ Ethernet output
- Real-time data Visualization with graphic, curves and profiles displays.

Each unit is equipped with Batch, Feed-batch, Continuous modes of operation.

STANDARD JACKETED VESSELS SPECIFICATIONS:

Total volume	Working volume (L)	min.Working volume (L)	Aspect ratio	Aspect ratio h/d Cell cultivation
7L	5	1,5	2.7 / 3.1	2.1 / 1.5
10L	7,5	2,5	2.7 / 3.1	2.1 / 1.5
15L	11	3,5	2.7 / 3.1	2.1 / 1.5
20L	15	5	2.7 / 3.1	2.1 / 1.5
30L	22	7,5	2.7 / 3.1	2.1 / 1.5
40L	30	10	2.7 / 3.1	2.1 / 1.5
50L	37,5	12,5	2.7 / 3.1	2.1 / 1.5
70L	52,5	17,5	2.7 / 3.1	2.1 / 1.5
100L	75	25	2.7 / 3.1	2.1 / 1.5
150L	110	37,5	2.7 / 3.1	2.1 / 1.5
200L	150	50	2.7 / 3.1	2.1 / 1.5
300L	225	75	2.7 / 3.1	2.1 / 1.5
400L	300	100	2.7 / 3.1	2.1 / 1.5
500L	375	125	2.7 / 3.1	2.1 / 1.5

FEATURES & SPECIFICATIONS

FEATURES

- Smart pH and D.O. probes allow monitoring of all sensor functions making substantial advantages in bioprocess monitoring and control
- pH sensor empower fully integrated accuracy monitoring
- Monitoring of sensor quality (glass resistance, reference resistance, Checkref potential).
- D.O. optical sensors demonstrate a number of substantial advantages because of a symbiosis of sensor and measurement amplifier- an smart sensor.
- Variable or fix speed peristaltic pumps, autoclavable type.

The pump heads parts are assembled together and mounted to the front end of the metering pump. Even if the separate parts are individually sterilized, handling is required for assembly which renders the product contact surfaces non-sterile. As a result, Kbiotech introduce onto his Bioreactors liquid metering pumps to avoid contamination problems caused by manual handling.

SPECIFICATIONS

Agitation system	Direct drive, single and double mechanical or magnetically coupled drive
Stirrer speed (rpm)	Standard range is 1 – 2000 rpm adjustable according
• •• •	to required configuration either bacterial, cell culture or both
Impellers	Rushton, Marine, Pitched Blade, adjustable and removable type impellers.
	Special impellers are also available.
Gas sparger	Porous sparger, L-type sparger, Sinterized sparger, fixed or removable type
Gasoverlay	Included as standard feature
Gas mixing	Standard set-up include Air, O2, CO2 and N2 gas mixing station, our unit can
	hold up to 8 gasses. Standard set-up include Flowmeters with on/off automatic
	solenoid valve for gas flow regulation or Massflow controllers for automated
	gas flow control and data recording
Exhaust gas	Water cooled exhaust gas Condenser
Sampling	Sanitary sampling system with contained sampling pipe
	including sampling bottles available with various volumes.
	DN Ingold sampling port or Retractable-fit type are available
Harvesting	Sanitary contained Drain pipe or Dip tube Fixed height or Height adjustable
Liquid additions	Sanitary inlet ports for chemicals additions
	or contained resterilizable liquid addition pipe
pН	Optical or classic pH sensor, 12mm, Ingold connectors.
	PLC and SCADA Software Control: via acid pump or CO2 gas
	(Flowmeter or MFC) in combination with alkali pump and/or other actuators.
D02	Optical or classic DO sensor, 12mm, Ingold connectors. PLC and SCADA
	Software Control: via or in combination with N2, Air, O2 (Flowmeter or automation
	MFC) and agitation or nutrient addition pump or other actuators
Temperature	Pt-100 sensor in thermo well plate. PLC and SCADA Software Control:
	cooling and/or heating jacket via bioreactor wall or via internal heat exchanger,
	cooling via tap water or chilled water
Foam	Height adjustable conductivity based foam and level sensor, High/Low foam
	sensors are also available. PLC and SCADA Software Control:
	Anti foam addition pump or other actuators.
Level	Height adjustable capacitative based level sensor.
-	PLC and SCADA Software Control: pump for liquid addition or removal
Pressure	Pressure sensor top plate mounted. PLC and SCADA Software Control:
	modulated pressure valve, combined with air inlet, Flowmeters/MFC,
	agitation and other actuators
Weight	Load cells and balances are available. PLC and SCADA Software Control:
	pumps for liquid addition or removal, chemostat or continuous mode.
Probes and sensors	Online Biomass probes, optical density sensors, CO2/O2/NH4/SO2 gas analyser,
available	pCO2 sensor, conductivity, methanol/ethanol analyzers, Automated samplers
<u> </u>	PLC and SCADA Software Control Integrations, OPC compliance.
Certifications	IQ, OQ, PQ protocols available including full material traceability
	GLP and cGMP compliance. User and maintenance manuals are available
	In English, French, German, Spanish or Italian. Chinese, Indian, Russian
A //	and Japanese languages, on request.
Atter-sales support	worldwide aπer-sales net-work with skilled engineers support.
	Remote diagnostic control and Unline assistance 24/24h available.

INDUSTRIAL PLANT PROJECTS

TURN-KEY SOLUTIONS BY KBIOTECH

The concept of modularity using standard modules to customized lav out of the bioreactors has been extended to the stainless steel Industrial bioreactors and fermenters. The vessels are cGMP and comply with different pressure code throughout the world. The systems are fully documented and delivered with all necessary documentation for mechanical and electronical components. The Industrial Systems are ranging in sizes of 500L up to 50cm³ or more. Our modular, pre-designed and configured turnkey system incorporating the most commonly requested functions and features.

COMPLEMENTARY PRODUCTS

- Complete, turnkey production-scale equipments
- Fully automatic in-situ sterilization and integrated steam generators
- Industrial PLC Automation controllers and SCADA Software in an IP55/IP65 stainless steel cabinet
- Integration of Online Analyzer's for complete process control
- Integration of Down-stream equipments
- Tangential flow and Dia-Filtration units
- Online Centrifuges
- Integration of Isolators and Laminar Flow cabinets
- Supply of Fill/Finishing and Capping automated or semi-automated machineries.

BioSIP HMI-PC

Full local controlwith large touch-screenPC interface

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High Quality

SS 316L bioreactors Fully cGMP conform

Sanitary piping Sterility and cleanability concept design

BioSteam

Automated steam generator unit

5 BioUPS

Back-up safety device for continuous operations

BioSIP 6

Advanced Controller Guaranteed flexibility and upgrades at any time

BioSip

In situ Sterilizable **Bioreactors**

Kbiotech

and his partners design and realise machineries for the pharmaceutical industry. Our firm's develop guideline is based on research and project of new solutions in full compliance with the quality and safety rules.

With a worldwide distribution network Kbiotech guarantees full local support and after-sales services.

The production catalogue includes over 100 machine models and a line of accessories and complements according to current GMP and FDa rules.

Our production line includes:

Bioreactors & Fermenters Filtration Units Isolators & Glowe Testers Sanitary Tanks Sterilizing & Depirogenizing Units Washing Machines Confectioning & Final Confectioning Machines Cryoplants Automation & Software Fornitures & Accessories Turnkey Projects

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