



Kbiotech

NEXT-GENERATION BIOREACTORS

**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.

Bio Sip

In situ Sterilizable Bioreactors

- 1 High Flexibility and Reliability**
via PLC automation and BIOFLEX SCADA software
- 2 Modularity and upgrades** at any time thanks to our new Modular concept design
- 3 Quality without compromise**
only certified materials are selected
- 4 Complete documentation.** IQQ, DQ and components traceability for GLP and cGMP
- 5 Service and Maintenance**
with a worldwide network



KBIOTECH SOLUTION FULL CONTROL & FLEXIBILITY



EXPERIENCE IN BIOREACTORS DESIGN AND STERILE PROCESSING

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.**

UNIQUE CONTROLLER FLEXIBILITY IN ONE BIOREACTOR

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 **BioSip** 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.

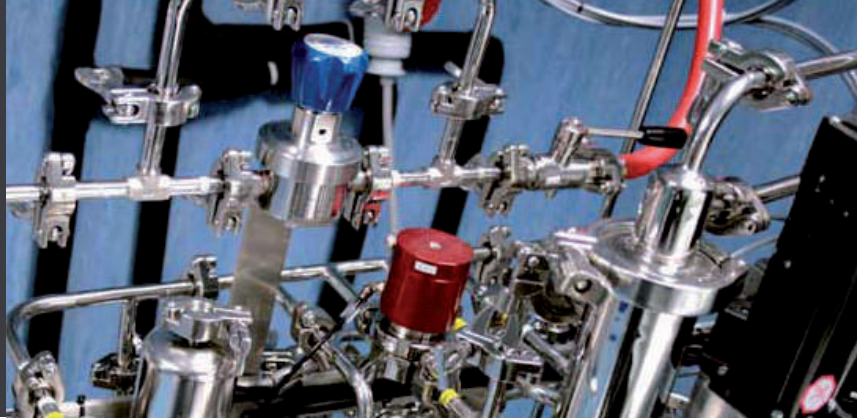
Each unit is equipped with Batch, Feed-batch, Continuous modes of operation.

STANDARD JACKETED VESSELS SPECIFICATIONS:

Total volume	Working volume (L)	min.Working volume (L)	Aspect ratio	
			Microbial culture	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

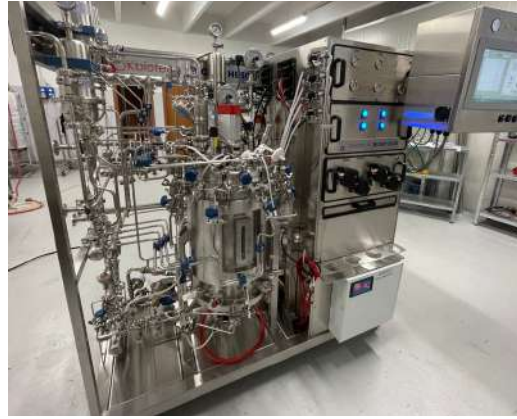
- Smart pH and D.O. probes allow monitoring of all sensor functions making substantial advantages in bioprocess monitoring and control
- pH sensor empower fully integrated accuracy monitoring
- Monitoring of sensor quality (glass resistance, reference resistance, Checkref potential).
- D.O. optical sensors 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
Gas overlay	Included as standard feature
Gas mixing	Standard set-up include Air, O ₂ , CO ₂ and N ₂ 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
pH	Optical or classic pH sensor, 12mm, Ingold connectors. PLC and SCADA Software Control: via acid pump or CO ₂ gas (Flowmeter or MFC) in combination with alkali pump and/or other actuators.
DO2	Optical or classic DO sensor, 12mm, Ingold connectors. PLC and SCADA Software Control: via or in combination with N ₂ , Air, O ₂ (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 capacitive 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 available	Online Biomass probes, optical density sensors, CO ₂ /O ₂ /NH ₄ /SO ₂ gas analyser, pCO ₂ sensor, conductivity, methanol/ethanol analyzers, Automated samplers 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 and Japanese languages, on request.
After-sales support	Worldwide after-sales net-work with skilled engineers support. Remote diagnostic control and Online assistance 24/24h available.

INDUSTRIAL PLANT PROJECTS

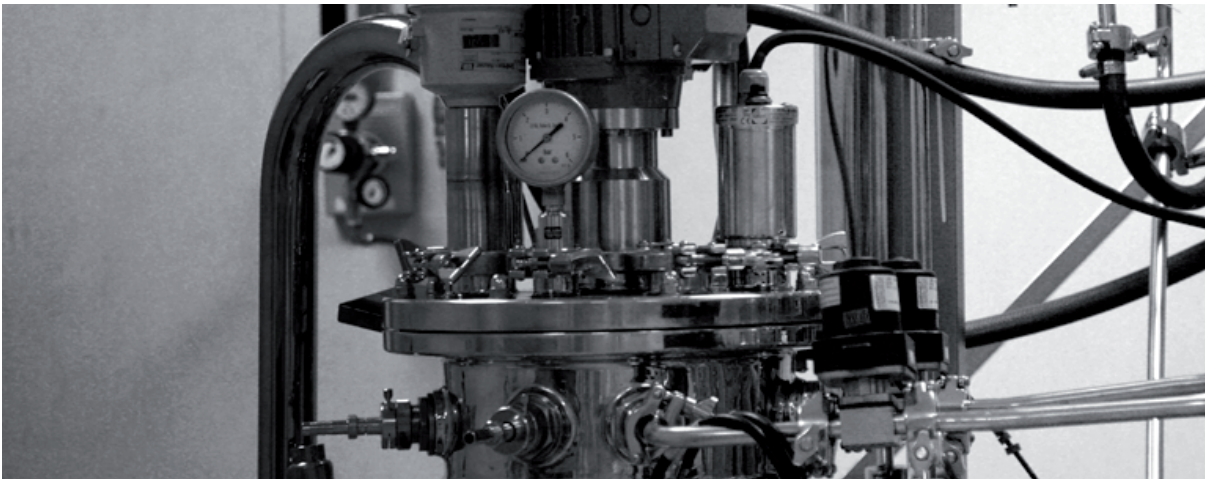


TURN-KEY SOLUTIONS BY KBIOTECH

The concept of modularity using standard modules to customized lay 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 electrical 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

IN SITU STERILIZABLE BIOREACTORS



1 BioSIP HMI-PC
Full local control with large touch-screen PC interface

2 High Quality
SS 316L bioreactors
Fully cGMP conform

3 Sanitary piping
Sterility and cleanability concept design

4 BioSteam
Automated steam generator unit

5 BioUPS
Back-up safety device for continuous operations

6 BioSIP
Advanced Controller
Guaranteed flexibility and upgrades at any time

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