

StirCradle™ PRO

Introduction

VacciXcell completes its bioprocessing solutions by providing systems for the fermentation of microorganisms and culture of suspension cells – StirCradle™ and StirCradle™-Pro. The StirCradle is the laboratory-scale autoclavable system while the StirCradle™-Pro is the SIP and optional CIP system for pilot / production scale.

The StirCradle™-Pro is a fully stainless steel fermenter/bioreactor system designed with an automated 5-step cycle SIP system for both culture medium and reactor vessel. VacciXcell offers a wide range of standard reactor capacities from 20L up to 1000L; however, customized reactor sizes are available should the user require.

StirCradle™-Pro features various advance design and assembly to facilitate the fermentation/culture process. The StirCradle™-Pro comes with a vessel design that eliminates blind spots while increases oxygen retention rate, a lifting system for the vessel lid for easy cleaning of the reactor vessel and a LED light for convenient viewing inside the culture tank.

VacciXcell simplifies scale up from the laboratory to pilot and production scale by providing analysis data as reference for scale-up conditions. Aside from customized sizes, VacciXcell also offers parametric programming and special vessel development to help speed up the experiment. VacciXcell offers complete documentation of system parts.

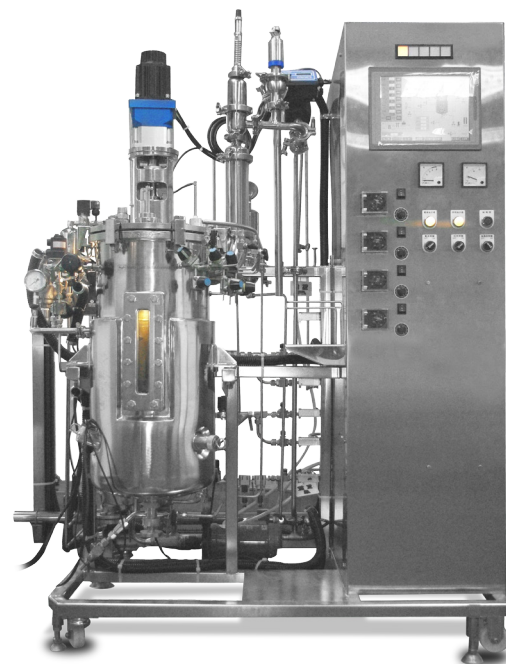
Applications

- Pilot and production scale fermentation processes of microorganisms such as yeast, bacteria, and fungi
- Pilot and production scale culture of cells such as insect cells and suspended mammalian cells
- Pilot and production scale for the manufacturing of biopharmaceuticals such as recombinant proteins, vaccines, and monoclonal antibodies

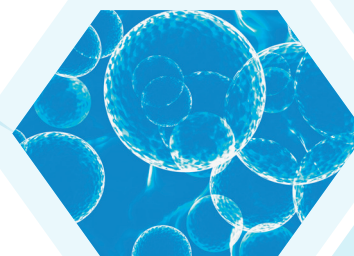
Features

Smart Control System

- Can use optional SCADA* system
- 15" Touch Screen Colored HMI with real-time 3D view of the fermentation/culture process and user-friendly display
- Real-time culture trend chart data logging. Built-in continuous recording system:
 - Up to 12.5 days: 1 data every 30seconds
 - Up to 25 days: 1 data every minute
 - Up to 50 days: 1 data every 2 minutes



StirCradle™-Pro 100



- Easy transfer of data (in .xls format) through USB
- Optional 21 CFR Part 11 Compliance*
- Remote sharing via ethernet port or wireless sharing device

Enhanced Design of Reactor Vessel and Components

- Up to 70% working volume
- Vessel is designed to eliminate blind spots
- LED light for convenient viewing inside the tank
- Multiple options for inoculation:
 - Quick Release Enhanced Short-Necked Dosing Port
 - Combustion Implant Bacteria Port
 - Diaphragm needle injection
- Φ25 Standard Configurable Electrode Ports for pH and DO
- All the contact surfaces inside the tank are polished by mechanical MP#400+EP and outside the tank by mechanical MP#300+EP
- Shell and Tube Condenser:
 - Inside Material: SUS316
 - Outside Piping: SUS304
 - Sanitary and easy disassembly to facilitate cleaning
- Safe design of pipings allows simple disassembly and replacement without affecting the process
- Impellers are designed to achieve high bubble dispersion efficiency and kLa value
- Sanitary clamp joint clips applied to the pressure sensor, diaphragm type manometer port, and prepare feed port.

Built-in Configurable Pumps

- Four (4) built-in configurable pumps for fluid addition, with up to 4 additional external pumps
- Each pump can be set as either Alkali, Acid, Feed or Antifoam
- Pump can be calibrated and flow can be set using speed %

Sterilization-in-Place (SIP)

- Automated SIP system for both reactor vessel and culture medium
- SIP program features 5 steps: Heating 1, Heating 2, Sterilization, Cooling 1, and Cooling 2
- Optional Cleaning-in-Place (CIP) system

Validation and Documentation

VacciXcell provides a thorough validation and documentation package for StirCradle™-Pro

- Validation Packages is inclusive of the following:
 - Material Certificate
 - Production Control Table
 - Welding Record
 - Pressure Testing Report
 - Operation Manual
 - Equipment Outline Chart
 - P&ID Chart
 - Layout
 - Electrical Loop Chart
 - Ra Testing Report
- IQ/OQ/PQ documentation is possible as an option.

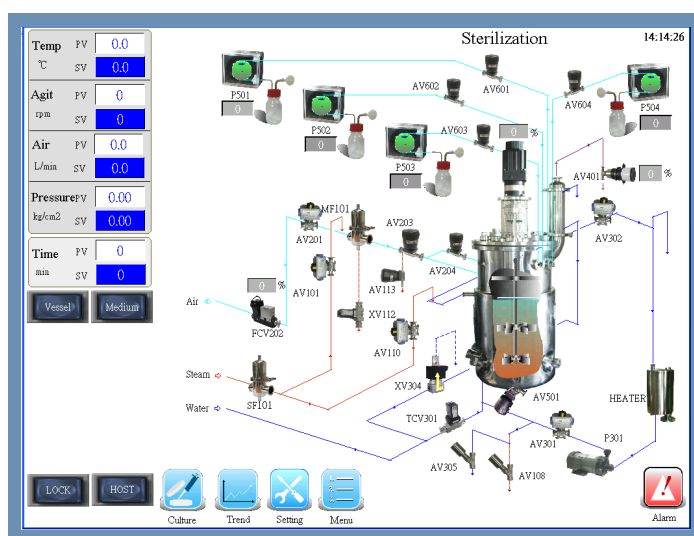
Other Features

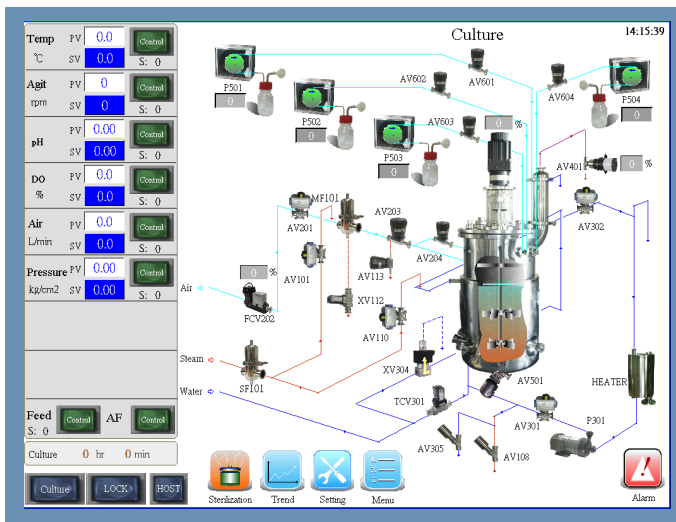
- Batch, fed-batch, continuously-batch, semi-continuous and high-density batch systems
- Enhanced high resistance torque bearing transmission unit and transmission bracket (SUS304+ surface EP processing).
- Online repeatable sterilization dry-type cartridge pattern mechanical shaft seal.
- Sterilizable quick release air pipe (anti-clogging highly dispersed air sparger), can be easily removed and cleaned.
- High sensitivity speed sensor (1,000Hz) using PID automatic calculation feedback compensated output to stepless speed change inverter (can control rotational speed at ± 1 rpm).
- Cooling water Y-type filter, steam filter, steam pressure reducing valve, air duplex preliminary filtrate group and air pressure reducing valve group.
- Pipe control unit:
 - Sterilization control valve
 - Temperature control piping manifolds
 - Sterile ventilation control piping manifolds
 - Exhaust tank pressure piping manifolds dosing the fed control valve (of four groups /sets)
 - Transfer transmission inoculation control manifolds pipeline.
- In case of power outage, positive pressure is kept inside the vessel for more than 24 hours. Parameters can be controlled.
- Airflow adjusting system 0-80L/min (1vvm) with optional mass flow controller for air intake (70 nL/min)

User Friendly Interface

Sterilization in Place (SIP) Screen

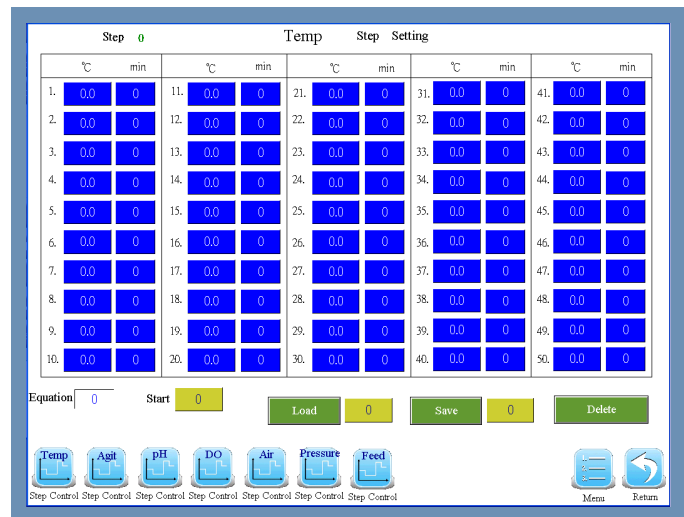
- SIP screen shows real-time view of sterilization process:
 - Shows the current step of the sterilization process
 - Shows open or closed valves
 - Shows the present and set values for sterilization parameters: temperature, agitation, air, pressure, and time
- 5-step sterilization process:
 - Heating 1 – 100% steam in heating jacket
 - Heating 2 – Steam in heating jacket and Air filter
 - Sterilization
 - Cooling 1 – Use of air for cool down system to 50 – 60°C
 - Cooling 2 – Use of chilled water/tap water to completely cool down system
- Sterilization modules for both reactor vessel culture medium





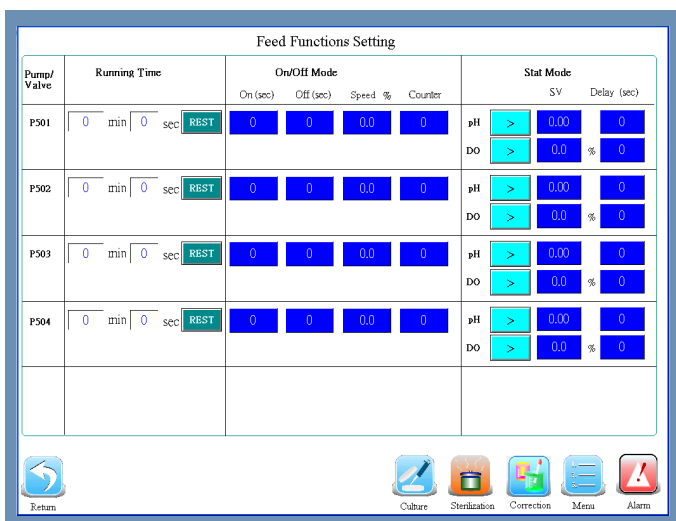
Culture Screen

- Real-time dynamic display of culture process
- Shows the set value and present value of all parameters, open and closed valves, and total volume of liquid added by each pump
- Users can switch between automatic and manual control of parameters
- Shows the total culture time



Step Control Setting Screen

- Users can set the parameter values for the sterilization cycle and culture process
- For sterilization process, users set the end temperatures for each sterilization step, agitation speed, pressure, airflow, and total time of sterilization.
- For culture settings, users can choose to have automatic or step control of the parameters:
 - Automatic: controlled by the set value (SV) of the user
 - Step: controlled by the step setting of the user
- Users can set one of the following DO control modes they require:
 - Agitation speed
 - Vent Control
 - Agitation speed -> Air -> O₂
 - Vent -> Agitation speed -> O₂
- Users can designate one of the following settings for the peristaltic pumps:
 - None: no pump action
 - Acid: acid addition
 - Alk: alkali addition
 - AF: antifoam addition
 - Feed: feed addition
- Foaming can be controlled using one of the two options:
 - Antifoam – addition of antifoam
 - Defoam – use of pressure



Feed Setting Screen

- Users can set the flow rates for each pump. Once the flow rate for each pump is set, the flow of each pump can be controlled in terms of speed percentage.
- Users can set the pump as one of the following:
 - On/Off: Users control pumping without depending on parameter values
 - DO Stat: Pumping is controlled by changes in DO value, depending on the criteria set by the user
 - pH Stat Pumping is controlled by changes in pH value, depending on the criteria set by the user

GENERAL SPECIFICATION

Features		Unit	StirCradle™ -Pro 20		StirCradle™ -Pro 30		StirCradle™ -Pro 50		StirCradle™ -Pro 100		StirCradle™ -Pro 200		StirCradle™ -Pro 500		StirCradle™ -Pro 1000	
Nominal Volume		L	20		30		50		100		200		500		1000	
Total Volume		L	25		34		56		126		220		620		1120	
Working Volume		L	15		20		35		75		150		400		750	
Tank Inner Diameter (D)		mm	260		260		310		400		480		680		830	
Tank Depth		mm	450		620		730		980		1200		1650		2000	
Mixing Blade Diameter		NA	D/3	D/2.5	D/3	D/2.5	D/3	D/2.5	D/3	D/2.5	D/3	D/2.5	D/3	D/2.5	D/3	D/2.5
		mm	87	104	87	104	103	124	133	160	160	192	227	272	277	332
Agitation	Speed	rpm	80 - 1000		80 - 1000		80 - 800		60 - 600		60 - 600		60 - 550		40 - 400	30 - 300
	Precision	rpm	±1													
Blade tip maximum speed		m/s	3.6	4.4	3.6	4.4	4.4	5.2	4.2	5	5	5	5.9	5.7	5.8	5.2
pH	Range	NA	0-14													
	Precision	NA	±0.01													
Temperature	Precision	°C	±0.01													
	Heating	NA	Hot water tank													
	Cooling	NA	Tap or Chilled water tank													
Dissolved Oxygen	Range	%	0 - 200													
	Precision	%	Display: ±0.1 Control: ±0.2- 0.5													
Noise Level		dBA	<100													
Air flow (0.3 kg/cm² culture)		vvm	2.3		2.3		2		2		2.1		2		2.2	
Total electricity demand 220 V, 3Φ		A	7		8		10		20		35		60		100	
Steam demand (2 kg/cm²-G 133 °C)		kg/hr	15		20		30		60		130		250		300	
Air Demand (2 kg/ cm²-G)		1/min	36		48		75		159		333		848		36	
Cooling Water Demand (2 kg/cm²-G 20°C)		m³/hr	0.3		0.4		0.5		0.8		1.5		2.5		4	
Continue Caliber	Steam	A	8		10		10		15		25		25		25	
	Air	A	8		10		10		15		20		25		40	
	Water	A	8		10		10		15		20		25		25	
Fermenter Sterilization		Sterilization-in-Place (SIP)														