



Designed in
Singapore



TideCell®

The Gentle Giant of Adherent Bioprocessing



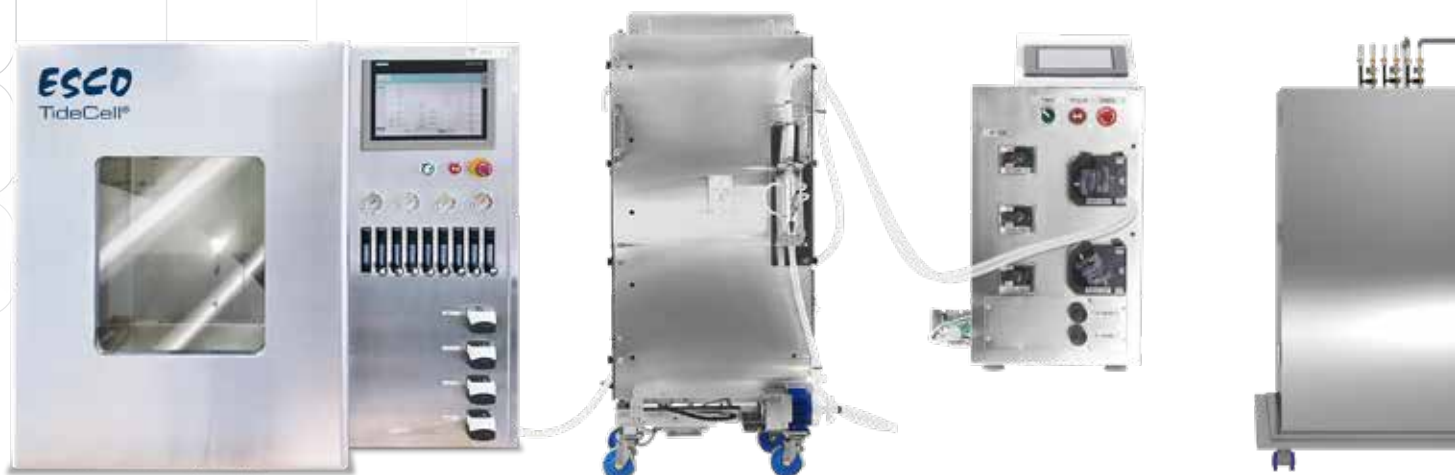
ESCO
Healthcare



TideCell®

High Density-Cell Culture System

TideCell® is the world's largest single-use linearly scalable bioreactor that runs on a patented Tide Motion principle for adherent cell bioprocessing. Single-use or multiple-use vessels of 2 L, 10 L, 20 L, and 100 L are available. TideCell® with closed cell harvesting system has a recovery rate of 90%, ideal for biomass expansion of adherent cells. TideCell® is integrated with desirable and advanced features such as pH and DO measurement capability, Siemens HMI and PLC-based monitoring and control system, compressed air path that comes with a double HEPA and VOC (volatile organic chemicals) filters as well as other accessories.



Proven Cell Lines and Indications

Esco TideCell® has been used for various human and animal commercial vaccines for PICs, eu cGMP and JIS factories globally. See VacciXcell's cell lines and indications below.

Vero - JEV

Vero - EV71

Vero - Rabies

MDCK - H5N1

► TideCell® is an ideal platform for many different applications:

- Culture of anchorage-dependent cells with BioNOC™ II carriers
- Transition from roller bottles to closed system
- Cell mass train
- Continuous bioprocessing
- Vaccine production
- Wild virus production
- Recombinant protein and monoclonal antibody production
- Cell therapy
- Biosimilars and biobetters
- Biologics for neglected tropical diseases and orphan diseases

► System Advantage:

- Can be single-use or multiple use
- Adherent cell scale-up for up to 5,000 L packed-bed volume (bio-equivalency of 50,000 L in suspension)
- A 100% media exchange system ideal for continuous bioprocessing
- Separation of the matrix and mixing vessel permits dual temperature control process to produce higher virus titers
- Built-in weighing platform and in-house mixer
- PLC based monitoring system with simple, intuitive touchscreen runs on Wonderware SCADA
- Can be connected to SCADA systems with DeltaV or Pcs7 controls
- Dual redundant systems for critical components such as PLC and pumps are catered
- Provides an ultra-scale down process and reduces costs by saving on media, labor, space, utilities, and most importantly, eliminates cross-contamination
- Isolator capability
- cGMP references
- PAT/IPQC



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MDCK - A(H1N1)

ST - Hog Cholera

Marc145 - PRRSV

N1

PK - Hog Cholera

BHK21 - Rabies

GL37 - HepA

Key Benefits

TideCell® utilizes the tide motion principle which is the gentle upward and downward motion of the culture medium in the matrix vessel. BioNOC™ II macrocarriers, which have a very low fiber content, are alternately exposed to nutrition and oxygen by this tide motion principle. Cells attached to these macrocarriers will not experience shear stress, resulting to minimal to zero cell debris.

Furthermore, lysed cells after viral infection will remain trapped within the matrixes. Hence, these cells will not be flushed into the harvest media during tide motion. This reduces host cell protein, DNA/RNA nucleic acid residues by several folds.

Highest Yield

The heart of the TideCell® system is the BioNOC™ II, which is made from 100% PET fibrous culture matrix with stability of up to 5 years. These macrocarriers provide cells with a large surface area for attachment and growth. The 3D matrix closely mimics a cell's in vivo environment. Furthermore, the efficient oxygenation and nutrition exchange in the matrix vessel allows cells to proliferate well and produce high yields of bioproducts.





Lowest Cost

Space, utilities, and labour requirements are lowered due to the system's compact and automated design. The high nutrition and aeration exchange levels of the tide motion principle reduces culture media consumption. TideCell® is a fully enclosed system and compressed air path comes with a double HEPA and VOC (volatile organic chemicals) filters. These filters remove particulates to maintain an ISO Class 5 environment during cell culture eliminating contamination risks. The system also comes with a germicidal UV-C decontamination suitable for BSL 3/4 applications.

Esco TideCell® concentrates cells within the matrix vessel, reducing total working volume to 1/5~1/25. This simplifies cell harvesting and downstream recovery processes, thereby reducing overall downstream processing cost. Columns are the most expensive component of any downstream process whilst concurrently maintaining high cell recovery. VacciXcell's fixed packed bed matrix vessel, with its concentric cylindrical design even in 100 L, can be separated from the mixing vessel in a closed manner and placed in a freezer for direct freezing and thawing, making cell harvesting simpler and more efficient.

Linear Scalability

TideCell® is a truly linearly scalable system from laboratory scale to production scale. It employs the same culture principle from seed preparation using the CelCradle™ System to succeeding larger scale TideCell® system up to 100 L volume. It also features the TideCell® Cell Harvesting System, which facilitates in the automated and closed system cell harvesting and seed transfer from one TideCell® System to another. True linear scalability allows faster and easier technology transfer with minimal bioprocessing time.

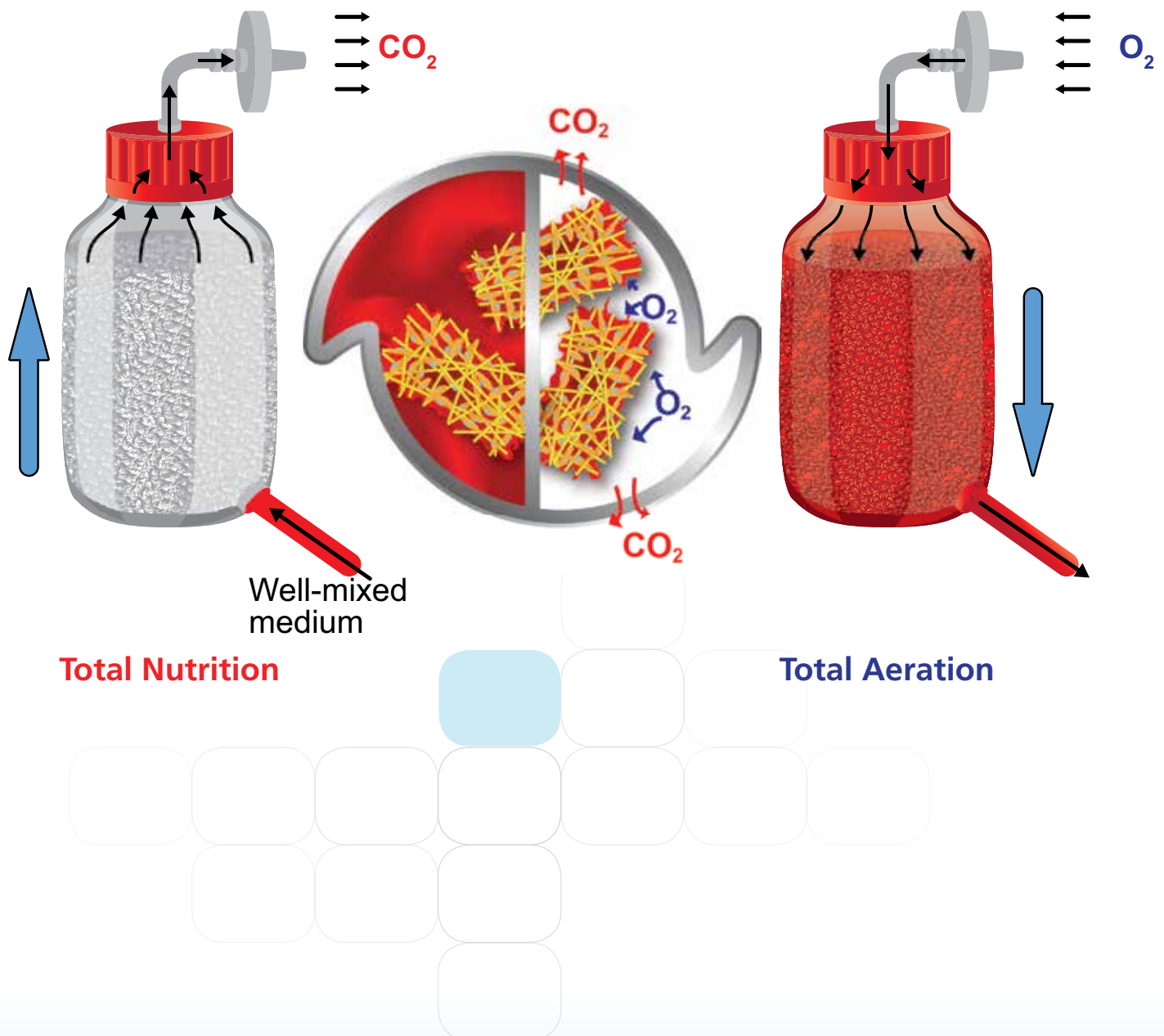


Tide Motion Technology

The Main Principle

Tide Motion is defined as the cyclical low and high rise of the bodies of water on earth. Similar to cell culture, patented Tide Motion principle is the gentle up and down of culture media in the reactor vessel. This oscillation principle provides nutrients and oxygen to cell being cultured, replacing the conventional stirred tank principle.

VacciXcell adherent bioreactor uses the proprietary BioNOC™ II macrocarriers that serves as a packed bed where cells can adhere to. These carriers mimic a 3D *in vivo*-like culture environment allowing cell to cell contact and a large surface area ratio for culturing cells. Together with the Tide Motion principle, BioNOC II macrocarriers are alternately exposed to air and nutrition.



Large Surface Area - 5.5g of carrier is already equivalent to 15,600 cm² of surface area

Highest Productivity - 5.5g of carriers is able to culture up to 5x10⁹ cells

Lowest Downstream Processing Cost - cells are fixed within proprietary BioNOC™ II macrocarriers and are separated from the media. This makes cell harvesting or media harvesting much easier

No Oxygen Limitation - Dual oxygenation action provides cells with ample oxygen regardless of the bioreactor scale.

Zero Shear Stress - Gentle upward and downward tide motion (2mm/s) provide nutrients and oxygen to cells without applying shear stress, perfect for shear-sensitive cells. Minimizes impurities with host cell protein and DNA/RNA.

No Bubbling, No Foaming – Tide motion bioreactors use separate vessels for culturing and stirring thus isolating the cells being cultured from any form of bubbling or foaming.

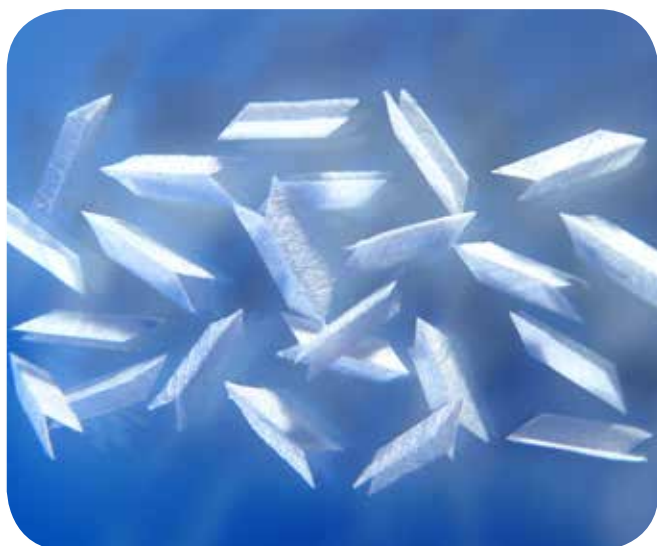
100% Continuous Processing >3 months - Ideal for biosimilars / biobetters, Monoclonal Antibodies (mAbs), and recombinant proteins. As cells are immobilized, cell retention devices, which are typical for perfusion based suspension Chinese Hamster Ovary (CHO) cells, are not required to separate cells from media. This means no fouling, foaming, and scalability issues resulting from flow rate limitations of cell retention devices.

100% Media Exchange – The separation of the matrix vessel and the mixing vessel, allows complete harvesting of the media within the mixing vessel and then refilling it with new media from the feed tank.

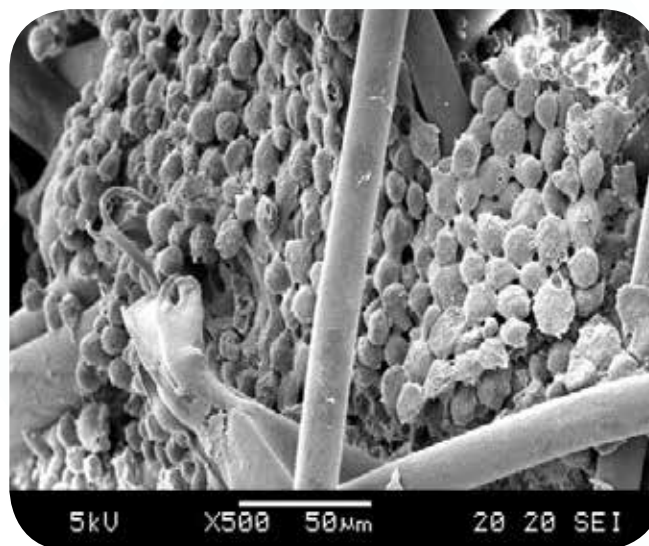
Controlled cell growth (Batch mode) - Controlled cell growth during cell culture to promote productivity in batch mode via extending exposure time during tide motion without requiring additional feed control.

Shortest bioprocess scale-up development time - parameters developed in academic /industrial R&D can be easily translated into clinical trials and commercial production as parameters are identical and hence linearly scalable without complex scale up bioprocess calculations (as those found in Stirred tanks).

Immortal cell lines - Freezing cells in G0 and G1 phase by nutrient starvation by deprivation of glucose to boost productivity of protein expression.



BioNOC™ II Macrocarriers



Cells attached on BioNOC™ II Macrocarriers

The System Concept

TideCell® Incubation and Control System

VacciXcell offers 2 different models of TideCell® Incubation and Control System: for 2 – 20L scale incubation & control system and 50 – 100 L scale incubation & control system.

TideCell® Incubation & Control System is integrated with a touchscreen HMI and PLC-based monitoring and control system. Its user-friendly design and control system can be connected and configured to SCADA systems that have DeltaV and Pcs7 controls. As a default, TideCell® runs on Wonderware SCADA. Double redundant systems are also catered depending on the target requirement.

The TideCell® Incubation and Control System features the compressed air path that comes with a double HEPA and VOC (volatile organic chemicals) filters. These filters remove particulates to maintain an ISO Class 5 environment during cell culture. TideCell® also comes with a germicidal UV-C decontamination suitable for BSL 3/4 applications. An optional Esco BioVap system can be added which guarantees 6-log bio-decontamination of the internal surface so operators do not need to rely on surface sterilization.

The incubation system further provides operator, environment, and sample protection with its magnetic door interlock and UV light. The glass window on the front door enables end users to observe the matrix vessel without the need to open the incubator. This in return reduces fluctuations in parameter values.



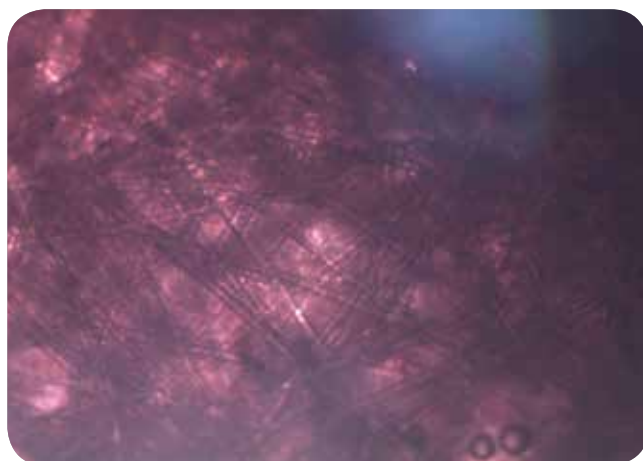
**TideCell® Incubation
with Control System**

(with Integrated weighing scale)

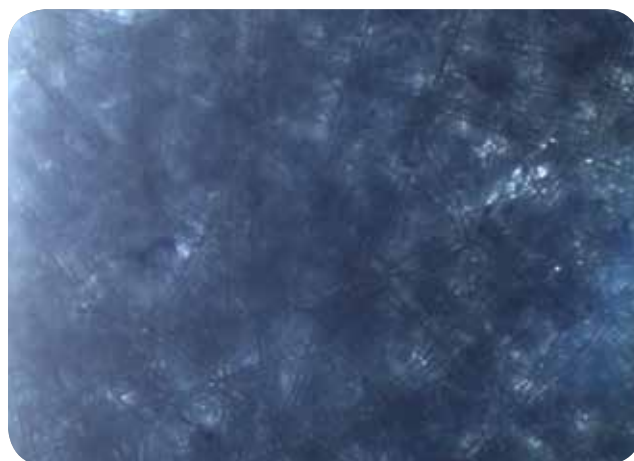


Culture Vessels

Different matrix vessels can be used in the same TideCell Incubation and Control System. Furthermore, the working volume of the matrix vessel depends on the quantity of BioNOC™ II macrocarriers used. These two features provide users with a more flexible production. One of the best examples is the production of a conditioned media. Culture medium compositions typically include essential amino acids, salts, vitamins, minerals, trace metals, sugars, lipids, and nucleosides. Conditioned media, on the other hand, contains many of the original components of the medium used, as well as a variety of cellular metabolites and secreted proteins, including, for example, biologically active growth factors and other extracellular proteins. This conditioned cell culture medium is typically used in culture manipulations such as for vaccine production and cosmetics.



C3A Human Hepatoma Cells Hematoxylin staining



C3A Human Hepatoma Cells Trypan Blue Staining

Note: Tide Motion technology has already been used for commercial production of Hepatitis A vaccine using kidney-derived cell line under cGMP conditions. Huh7 cells can also be used for Hepatitis viral production utilizing the tide motion principle.

TideCell System	TideCell System: 2-20L					TideCell System: 100 L	
Matrix Vessel	2 L		10 L	20 L		100 L	
	Multiple-Use	Single-Use	Multiple-Use	Multiple-Use	Single-Use	Multiple-Use	Single-Use
Matrix Volume	1-2 L		5-10 L			50-100 L	
Closed Sampling Port No.	0	1	0	0	1-4	0	1-5
Pre-packed carrier (g)	0	55 110	0	0	275 550 1100	0	2,750 5,500
Material	Glass	PP	Glass	PP	PP	PP	PP
AutoFeeder	Integrated/AF-1200					AF-1200	

VacciXcell provides a wide range of matrix vessels, depending on user's production density requirements.



► Single-use matrix vessel

- Gamma-irradiated, ready-to-use and are pre-packed with BioNOC™ II macrocarrier
- Features patent pending close sampling ports which consist of a basket immersed within the matrix vessel and connected to sampling port tube on the lid of the matrix vessel

► Reusable matrix vessel

- Autoclavable matrix vessel available in 2 L, 10 L, and 20 L volumes
- Must be refilled with fresh and autoclaved BioNOC™ II macrocarriers to which a qualitative test for cells must be done.

Note: This is performed through direct sampling of carriers inside a Biological Safety Cabinet



Mixing Systems

The TideCell® Mixing System is where the mixing vessel containing the culture medium is continuously mixed, and parameters such as pH, dissolved oxygen (DO), and temperature are monitored and regulated. Separating culture medium vessel and culture vessel dramatically decreases problems typically occurring during mixing. The separation of the matrix vessel and mixing vessel also permits temperatures to vary for cell and viral culture. Cells can be cultured to confluence at 37°C in 1 mixing vessel, after which 100% of a fresh medium at a lower temperature in a separate mixing vessel can be used for viral culture after virus seeding. This dual temperature control process can potentially produce higher virus titers for specific viral strains or aquaculture vaccines than what can be achieved in typical perfusion systems utilizing microcarriers or other packed bed bioreactors which are only able to culture at 1 set temperature.



Magnetic Stirrer Mixing System

10 L | 20 L

Vessel Material: Borosilicate Glass

System Material: Stainless Steel 304

All the mixing vessels have ports for pH probe, DO probe, temperature probe, harvest, and feed ports for direct emptying and filling of the vessels. Sampling ports are also available for medium sampling, and the additional ports can be used to pump in other reagents.

To offer more options, VacciXcell has adopted three (3) different types of mixing system: magnetic stirrer mixing system, recirculation thermostatic mixing system, and stir tank mixing system.

The in-house magnetic stirrer mixing system uses a stainless steel magnetic stirrer for relatively small-scale mixing. Glass mixing vessel of up to 20 L is placed on the stainless steel magnetic stirrer. The stirrer speed can be set from 100 to 1,500 rpm. The temperature is controlled by a heating jacket which has a maximum temperature of 45°C.

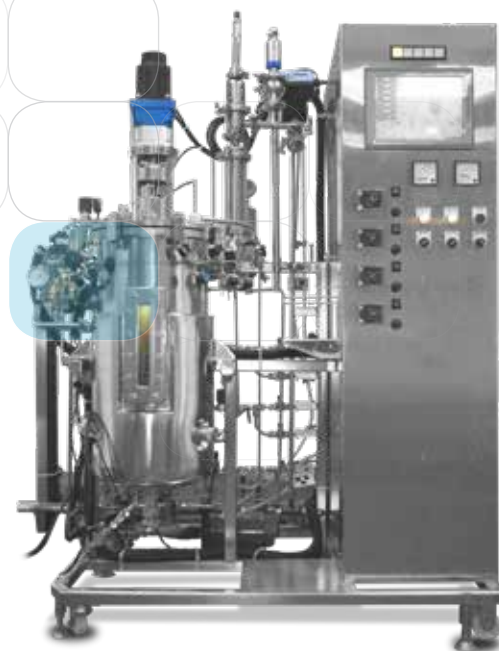
This multiple-use stainless steel mixing system is similar to stirred tank bioreactor for pilot or production scale. The culture medium is continuously agitated by an impeller and parameters such as dissolved oxygen, temperature, and pH are monitored and regulated. The tank consists of 2 impellers which are located on the bottom and at the center of mixing tank to allow media homogenization.

More than ten (10) types of impellers are available should the user require a specific impeller type. Agitation rate, in general, ranges from 80 to 1000 rpm and temperature control up to 60°C

The Stir Tank Mixing System has a built-in automated Sterilization-In-Place (SIP) system, allowing proper sterilization of the mixing tank and the culture medium. SIP (sterilization in place) protocol consists of 5 steps:

Heating 1	Cooling 1
Heating 2	Cooling 2
Sterilization	

This protocol can be set and automatically runs according to the set value. Other features of this system include motorized tank lid lifter, which enables viewing of the inside of the tank vessel, optional Wash-In-Place WIP, and glass window and LED light which allows culture observation.



Stirred Tank Mixing System

30 L | 50 L | 100 L | 200 L | 500 L | 1000 L

Vessel Material: Stainless Steel 316 and Stainless Steel 304

System Material: Stainless Steel 316



Recirculation Thermostatic Mixing System

50 L | 100 L | 200 L | 500 L | 1000 L

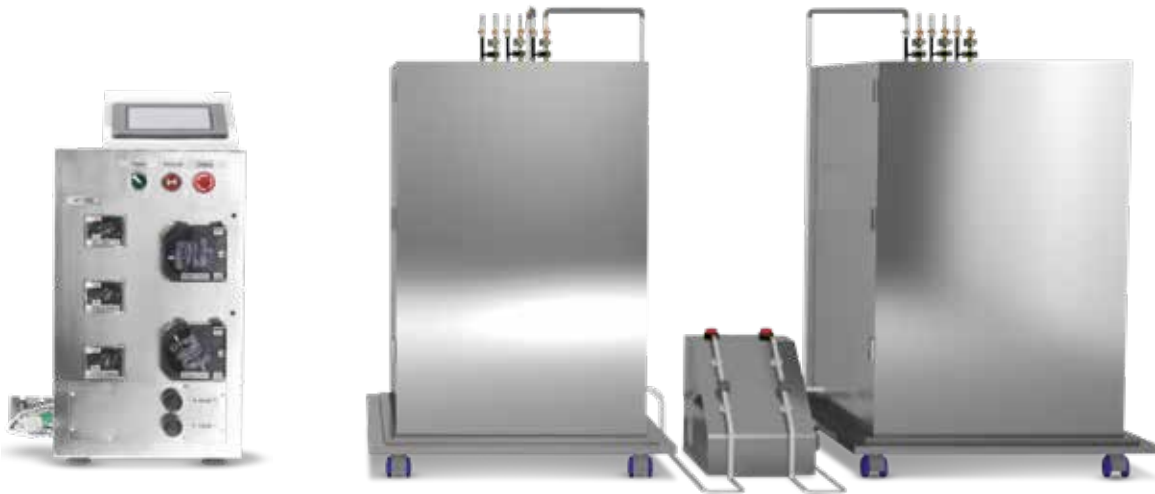
Vessel Material: Plastic

System Material: Stainless Steel 304

Recirculation thermostatic mixing system is designed for relatively larger scale production. Recirculation mixing system consists of a rectangular stainless steel vessel which holds a disposable mixing bag. Each side wall of the vessel has a thermostatic panel, which regulates temperature faster. The internal experiment proves that heating up 100 to 500 L of media from 20°C to 37°C will take only less than 4 hours. The recirculation thermostatic mixing system uses a magnet-driven impeller, allowing mixing without housing contact and bearing, which may be a source of contamination. The single-use magnetic pump head is directly mounted to the motor. The pump rate can go from 0-21 LPM and temperature of up to 50°C. pH, DO, and temperature probes located in the probe holders on the side wall are autoclavable. Installation and removal of the mixing bag from the vessel can be done using the side door.

Feed/Harvest System

The Feed/Harvest system is an optional system that allows users to run the culture in perfusion or continuous mode for long periods of time.



Feed/Harvest Tank

This system controls the volumetric flow of medium coming in and out by checking the weight of the mixing container. In fed-batch mode, the volume of the culture medium to be added is set and pumped into the mixing container using the autofeeder system. In perfusion mode, the total weight of the mixing container is measured, and the system automatically adjusts the volumetric flow of the medium to and from the mixing vessel, allowing same media volume exchange between feed and harvest tank.

AutoFeeder System

The AutoFeeder system has three (3) primary control functions: automatic control of feed and harvest volume by weight calculation, pH control, and dissolved oxygen (DO) level control. During feeding and harvesting, two (2) large peristaltic pumps are used to pump medium in and out of the vessel with a speed of up to 2000ml/min. This allows of up to 900L of culture medium to be transferred each day, which can be divided into 1 – 96 cycles per day. A step program system can be used to set medium exchange volume in a step-wise manner; users can set the medium exchange volume at each step and can create up to 10 steps. A small pump is used for the alkali addition under pH control. Users set the sampling and flushing time and lower and upper the limits of the alarm. The system controls DO levels through oxygen and air levels.



AutoSwitch System

The AutoSwitch System is recommended if there are two feeding tanks used during fed-batch or perfusion culture. This system is connected in between two feeding tanks. The pinch valve inside the system will detect the media level within the tank and will automatically switch from the other tank once empty. There are individual alarm lights for each tank to indicate whether the media in the tank is depleted. In addition to this, the autoswitch system includes in-line and non-invasive bubble detector.



TideCell® Cell Harvesting System

The TideCell® Cell Harvesting System (TCCHS) allows the automatic harvesting of cells from the matrix vessel in a closed system. TideCell® Cell Harvesting System utilizes the same conventional cell harvest concept by enzymatic treatment to detach cells from BioNOC™ II carriers. The TideCell® matrix vessel is transferred to the TCCHS. The harvesting protocol will be similar to the user's current harvesting protocol. A buffer is pumped in to clean out media from matrix vessel, followed by an enzyme which is more commonly trypsin for cell detachment. During detachment procedure, TCCHS shakes the matrix vessel at a distance of 10 cm and a speed of up to 300 rpm. An inhibitor can be used depending on the protocol used. The detached cells are then collected with medium. With this system, a buffer solution is pumped in and out of matrix vessel for 1-3 times (VacciXcell recommends collecting cells with media after the fifth wash). This automated harvest system allows cell harvesting within 1 to 3 hours, depending on harvest cycles. This shows around 95% viability after harvest.



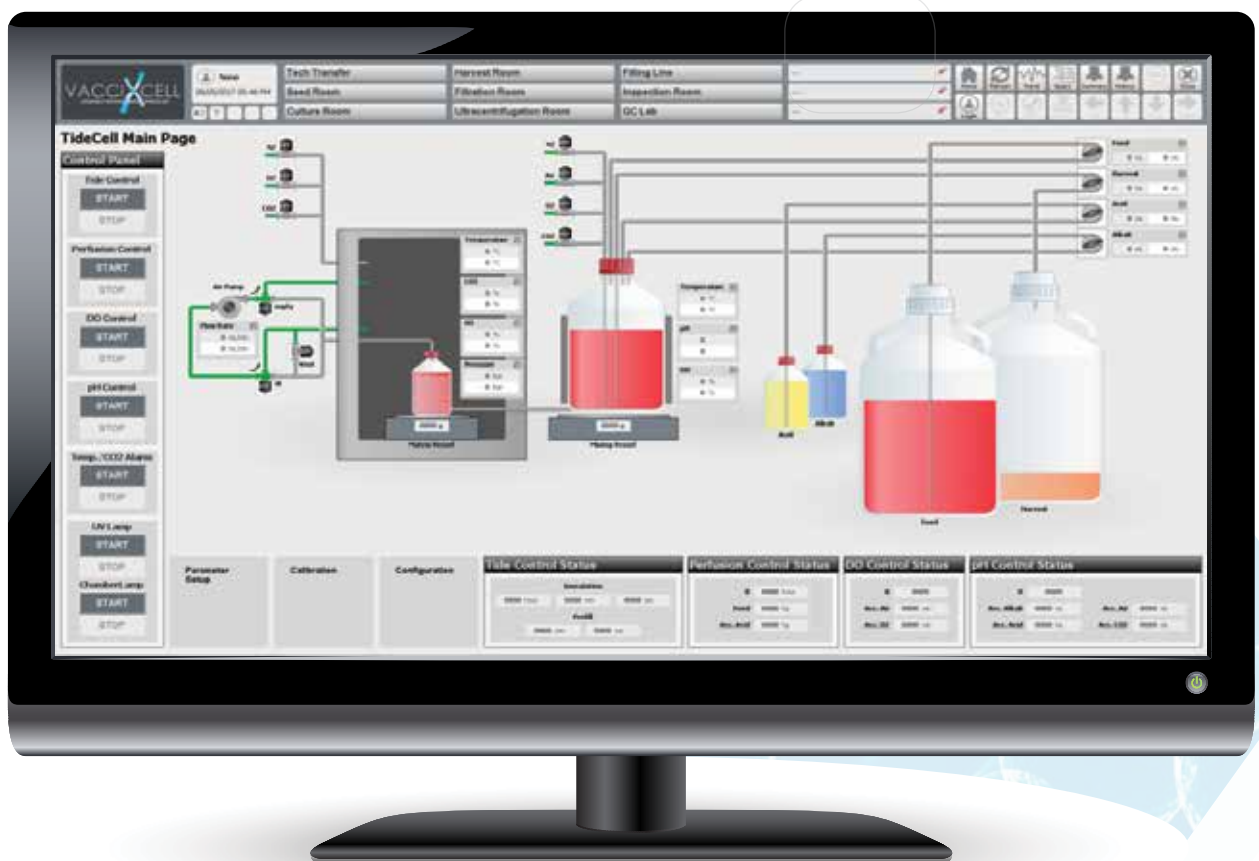
PLC-based Monitoring and Control Structure

Local Control

TideCell® is controlled by Siemens HMI/ PLC-based monitoring and control structure. This control structure ensures a fast, flexible, and reliable solution for continuous processing. PLC-based monitoring and control system can be connected and configured to SCADA systems that have DeltaV and Pcs7 controls. Dual redundant systems for critical components such as PLC and pumps are catered for at additional costing.

Its features include:

- Real-time vessel display
- Alarm monitoring
- Trend display
- Advanced DO control
- Gas flow control
- Perfusion control
- Sensor calibration
- Controller status indication



The Wonder System

SCADA

TideCell® PLC-based monitoring and control structure runs on WonderWare SCADA. This provides a high-level process supervisory management and data acquisition. This software platform will ensure process control safety, will support control strategy, and will provide a remote method of capturing data and events (alarms) for monitoring the continuous process. SCADA platforms also provide functions for graphical displays, alarms, trends and historical storage of data.

TideCell® is the core of Esco Aster, a contract development manufacturing organization (CDMO) that uses single-use adherent bioreactors in bioprocessing needs. Esco Aster focuses on process development, commercialization of NTDs for both humans and animals, orphan drugs, as a CMO for partner TideCell® factories looking to gain access in the ASEAN, ANZ, Africa region.



TideCell® Product Specification

TideCell® Incubator & Control System

Construction	Stainless steel 304 HL inner chamber and stainless steel 304 HL door and system
Electrical requirements	Monophase 3-wires AC 220V \pm 10% V 15A max 50/60 Hz
Control Hardware (2-20 L)	Flexible pc-base/DAQ industrial control interface; Solenoid valves/PID gauges/Pressure-vacuum motor NDIR CO2 diffusion-type sensor
Control Hardware (50-100 L)	Compact Rio PAC/DAQ industrial controller Solenoid valves/PID gauges/Pressure-vacuum motor NDIR CO2 diffusion type sensor
Control Software	Siemens PLC-based control and monitoring structure Siemens HMI with 12.1" touchscreen Developmental environment: TIA Portal V13 SP1
Incubator	0 – 20% CO2 PID Control RT +8°C-45°C Temperature PID Control Front view window; LED inside lighting Emergency power-off button
Connection	CPC nickel-coated brass quick connectors Electric connectors with locking-screw
Communication	9-pin Dsub RS-485 port : Modbus RTU protocol 2 USB Ports for import firmware / software upgrade and export trend data
Control Features	Simple user's administration Process page & Data viewer page Data logging / Parameters logging / Events logging Individual seed & cultivation conditions setting with default values Automatic switch from seeding stage to cultivation stage (up to 300 min) Gas flow rate : 0.8 – 20 LPM depends on system size; PID control; Delay time: up to 99m 59s Individual up/down condition settings; automatic & manual operation Automatic air refreshing mechanism
Protection	Over pressure protection (max. 1 bar) Liquid leaking protection Over suction protection Over time protection

TideCell® Mixing System

	Magnetic Stirrer Mixing System	Recirculation Thermostatic Mixing System	Stir-tank mixing system
Construction	Magnetic stirrer 10, 20 L glass vessel with stir bar for mixing	Recirculation Mixing with magnetic driven bearing-less impeller	Stir mixing with pre-installed impeller
Electrical Requirements	Monophase 3-threads AC 220V \pm 10V 5A max 50/60 Hz	Single phase, AC 220V, 9A max , 50/60 Hz	Three phase, 230 VAC, 50/60 Hz
Capacity	10 L and 20 L	50 L, 100 L 200 L, 500 L, 1,000 L	30 L, 50 L, 100 L, 200 L, 500 L, 1,000 L
Control	100 – 1,500 rpm stir rate RT – 45°C temperature control	Pumping rate 0 – 21 LPM RT – 50°C temperature control	80 – 1,000 rpm stir rate RT – 60°C temperature control SIP system (sterilization in place)

AutoFeeder Specification

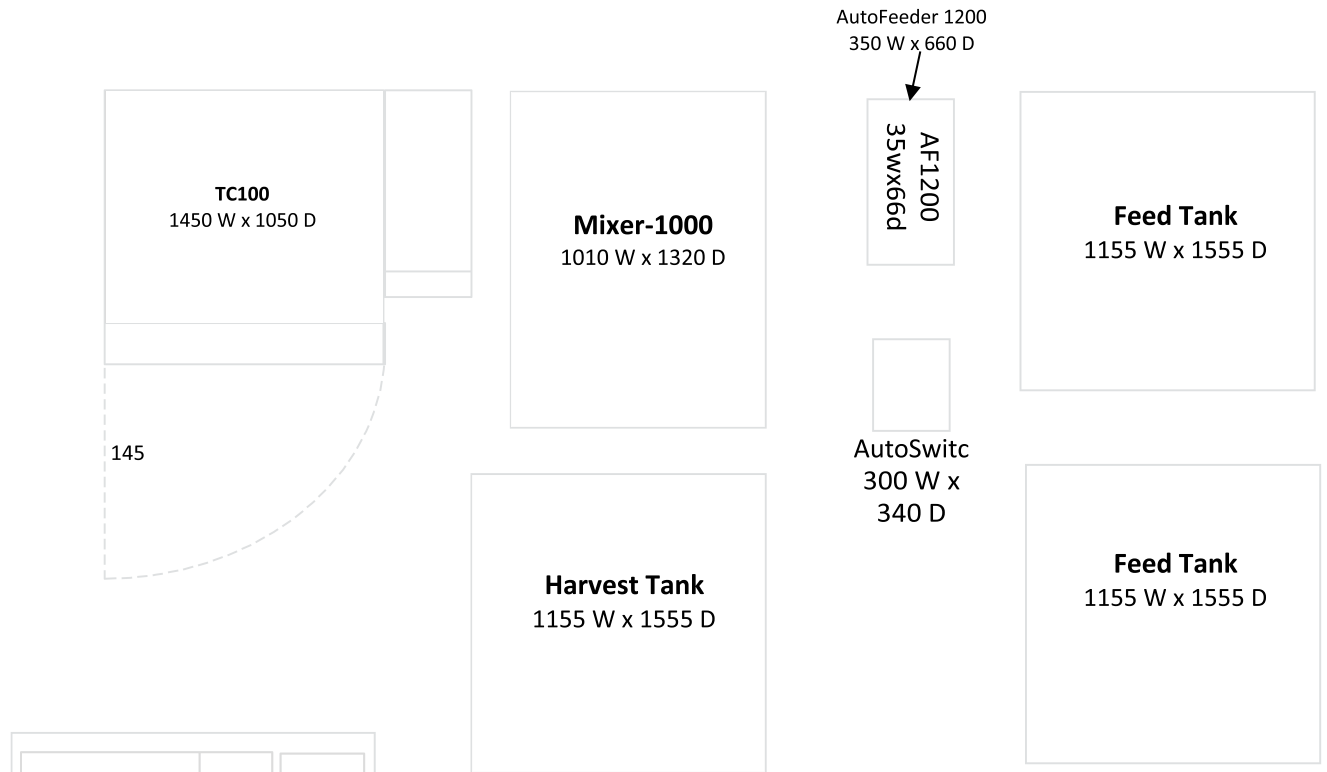
Electrical requirements	AC 220V, 50/60 Hz
Control unit	Reliable industrial PLC; Industrial touch screen HMI Electronic balance: 0 – 1,500 kg
Control Parameters	Transferred volume: 10 – 900 L/day Transferred cycle: 1 – 96 cycles/day Up to eight steps for each program : 40 sets memorized in data bank Time span for each step: 2 – 9,999 hr pH: 4 – 10 ± 0.1 DO: 0 – 100 % ± 2.0
Features	Dynamic Feed & harvest weight profiles : feeding & harvesting start/stop recorded Manual & Automatic process : auto-switching for feeding selection Overflow detection for harvest Error message recorded
Communication	Modbus ASCII
Protection	Maximum net weight stop protection : Harvest Minimum net weight stop protection : Feeding Invalid parameters prohibited

Feed Tanks AutoSwitch System

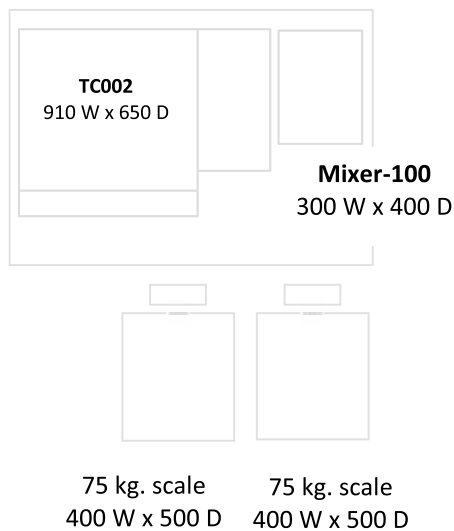
Electrical requirements	Magnetic stirrer 10, 20 L glass vessel with stir bar for mixing
Control unit	Monophase 3-threads AC 220V ±10V 5A max 50/60 Hz
Features	Control two feed tanks by switching the feed line from one to another once the one is empty during feeding. Alarm light will on once the liquid in one of the tanks is depleted Alarm buzz will on once two are all empty
Sensors	In-line and non-invasive bubble detector x 2
Protection	Individual warning lights for indicating depletion of feed tanks

Cell Harvest System

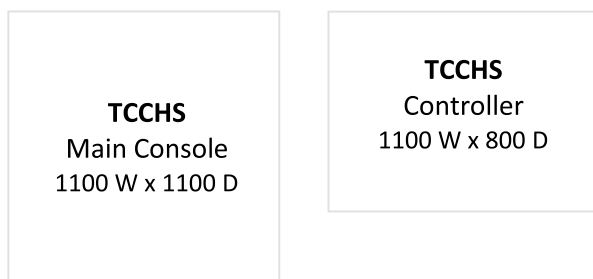
Electrical requirements	220V, 50/60 Hz, 15A
Control unit	Reliable Industrial PLC
Liquid transfer	Six peristaltic pumps, transfer buffer, enzyme, enzyme inhibitor, culture medium, harvest cell solution and waste for cell harvest purpose
Control parameters	Sequential control on each pump On/Off Pump time 0-999 secs Pump rpm : 20 – 250 rpm Shaking speed : 50 – 300 rpm Rotation : continuous, ½ turn Manual and automatic control
Features	Equips with 6 peristaltic pumps for reagent input and output Compatible to 2 L and 20 L single use matrix vessels
Communication	CF card, RS485 data transfer
Protection	Door open protection Low speed alarm Abnormal alarm



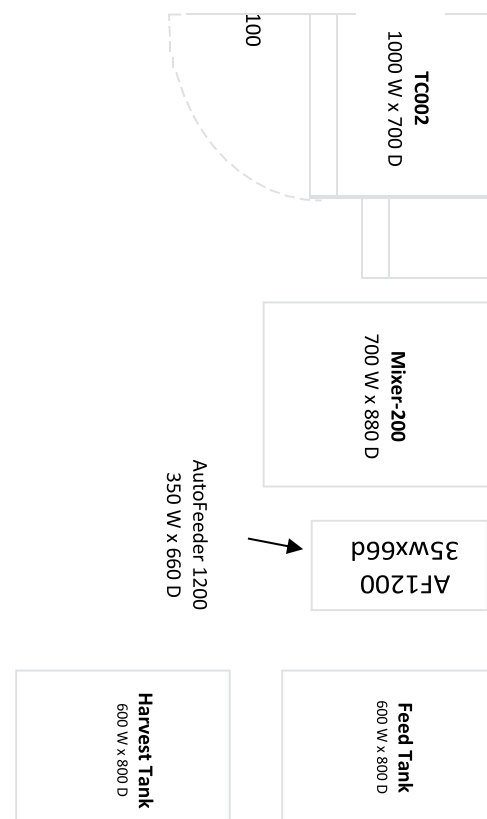
**TideCell-100 HD Cell Culture System
Footprint (mm)**



**TideCell-002 HD Cell Culture System
Footprint (mm)**



**TideCell Cell Harvest System
Footprint (mm)**



**TideCell-020 HD Cell Culture System
Footprint (mm)**

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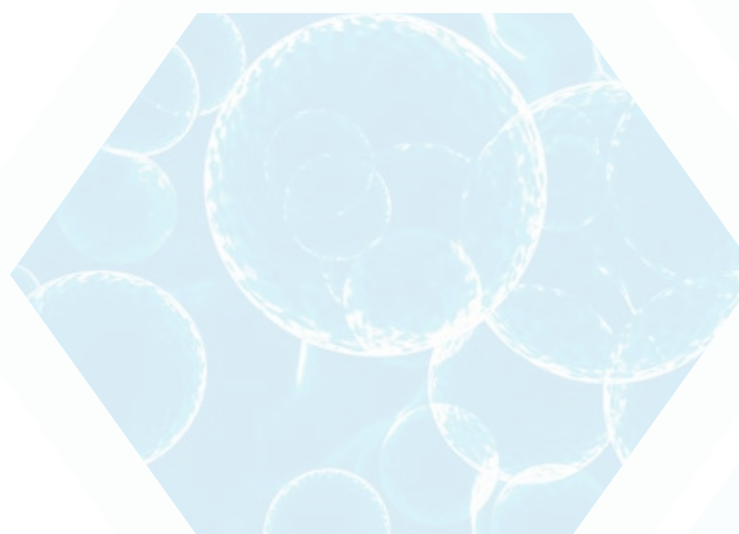
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