

USD2944a⁽¹⁾

PadReactor® System



Single-use, stirred bioreactor

Highlights and Benefits

- Cube-shaped design incorporating a mixing paddle coupled with a dynamic sparger device:
 - Low shear stress bioreactor as the superior mixing capabilities enables to mix at very low speed
 - Superior oxygenation and high kLa maintained due to a fully integrated sparging device distributing better the bubbles
- Proven to be effective for cultivation of suspended and adherent cells on microcarriers
- Linearly scalable from 10 L to 1200 L
- ▶ User friendly single-use bioreactor designed to be used in cGMP environments
 - Quick biocontainer installation and fast set-up enabling start up time to be decreased by 2 to 4 hours per batch
 - Limited footprint with an easy access to every part of the bioreactor
 - Easy observation of the cells during the cultivation and harvest throught a fully transparent front cover
 - No need for CIP/SIP, avoiding cross contamination risks

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Line	Description		
14	Multi port fitment - can be used for: nutrient addition, gas exhaust/foam trap, acid addition, media filling, inoculation		
58	Multi port fitment - can be used for: nutrient addition, gas exhaust/foam trap, acid addition, media filling, inoculation		
9	Disposable bioreactor biocontainer (Pall Life Sciences Allegro TK8 ADCF film)		
10	Sampling port		
11	Perfusion connection/extra sampling connection		
12	Connection for pH, T or DO probe with Kleenpak [™] sterile connector		
13	Sensing probe assembly to be connected to (12) by Kleenpak sterile connector		
14	Easy drain connector		
15	Micro (20 $\mu\text{m})$ or macro (2 mm holes) rigid and in motion sparger device		
16	Pall Life Sciences paddle mixing stick surrounded by sleeve		
17	Gas inlet through sparger device		

Overview

The PadReactor system is a single-use bioreactor specifically designed to fulfill the needs of cell culturists. It is perfectly suited to laboratory environments, process development centers, clinical material supply and flexible cGMP manufacturing. The PadReactor system offers a platform, which gives the end user the opportunity to choose a preferred controller or use Pall recommended controller (ez-Control from Applikon).

Its innovative cube-shaped biocontainer design integrates a highly efficient internal mixing paddle coupled with a dynamic sparger. The system is non-invasive as the paddle and the sparger are enclosed in a medical grade ultra low-density polyethylene resin (ULDPE) sleeve, made from the same contact material as the biocontainer itself. The paddle is coupled on top of the vessel with the mechanical mixing head.

The superior mixing capabilities and the innovative sparging device enable the PadReactor bioreactor to achieve greater productivity compared to cylindrical bioreactors.

The PadReactor utilizes disposable mixing biocontainers made from Allegro™ TK8 bioprocess film. The product-contacting layer of the Allegro TK8 film is blow-extruded in-house by Pall Life Sciences under cleanroom conditions using medical-grade ULDPE. It is then laminated to create a gas barrier film of exceptional cleanliness, strength, and clarity that is animal derived component free (ADCF) and complies fully with USP Class VI requirements.

The PadReactor single-use bioreactor consists of the following:

Drive Unit – The flexible drive unit allows the system to cultivate cells in disposable biocontainers. One drive unit is adapted for various disposable mixing biocontainer sizes. Each system comes with the appropriate mixing stick for your container.

Mobile Retaining Tank – The purpose of the retaining tank is to support the mixing biocontainer and provide mobility before and after operation. Various tank sizes and options are available.

Bioreactor Vessel – The reactor vessel uses an innovative biocontainers design that allows a non-invasive connection to the mixer. Mixing is achieved when the integrated paddle/ sparger inside the biocontainer rotates within the biocontainer.

Controller (optional) – ez-Control from Applikon configured to work with PadReactor system.



Mixing is achieved when the integrated paddle/sparger inside the biocontainer rotates.

PadReactor Biocontainer and Holder

- Available biocontainer sizes, 25 L, 50 L, 125 L, 250 L, 600 L and 1200 L with cube-shape geometry
- Film material: Allegro TK8 multi-layer film with contact layer in ULDPE, gamma sterilizable, USP - Class VI compliant, fully ADCF (Animal Derived Component Free)
- Temperature control via jacketed container



PadReactor System Weight and Dimensions

Dimension	25 L	50 L	125 L
Biocontainer Holder (w x d x h)	465 x 365 x 785 mm	515 x 425 x 785 mm	700 x 525 x 785 mm
Drive Unit (w x d x h)	845 x 940 x 1360 mm	845 x 940 x 1360 mm	845 x 940 x 1360 mm
Biocontainer Holder	48 kg	57 kg	80 kg
Drive Unit Weight	250 kg	250 kg	250 kg
Jacket Liquid Volume	0.4 L	0.6 L	1.4 L
Dimension	250 L	600 L	1200 L

DIIIIelisioli	200 L	000 L	1200 L
Biocontainer Holder (w x d x h)	880 x 690 x 1375 mm	1010 x 880 x 1375 mm	1200 x 1155 x 1375 mm
Drive Unit (w x d x h)	1140 x 1035 x 1960 mm	1140 x 1035 x 1960 mm	1140 x 1035 x 1960 mm
Biocontainer Holder	125 kg	232 kg	288 kg
Drive Unit Weight	325 kg	325 kg	325 kg
Jacket Liquid Volume	2 L	4.25 L	5.25 L

Mixing Capabilities Model

The PadReactor system utilizes a cube-shaped vessel design agitated with a paddle-shaped mixing element rotating in an elliptical motion. The corners of the vessel act as baffles to prevent vortexing and ensure robust mixing with very low shear stress. In order to model the mixing capabilities of the PadReactor system, Computational Fluid Dynamics (CFD) analysis has been conducted in different volumes and at different mixing speeds. As demonstrated on pictures mixing, turbulent but low shear mixing is easily achieved, even at low speeds. The cube-shaped vessel and paddle mixing element design of the PadReactor system provides effective mixing advantages. These advantages have been shown to require lower power input, improved gas transfer and improved productivity when compared to bioreactors with cylindrical vessels. (For additional information, please refer to the Pall Life Science poster "Engineering Analysis of Mixing in Pall Life Science Bioreactors using Computational Fluid Dynamics".)



Velocity Vectors in the PadReactor System



Liquid flow path in the PadReactor System

Indiactive nerformance rates

Thermostatic Cooling/Heating Bath Guidelines (TCU, Required)

For 25/50/125 liter biocontainer holders	For 250/600/1200 liter biocontainer holders	for 25 liter biocontainer holder	
Working temperature range: -45 °C / +200 °C	Working temperature range: -30 °C / +120 °C	Heating rate: 22 °C/hour (20 to 37 °C in 45 min)	
Heater power: 3.5 kW	Heater power: 6 kW	Cooling rate: 4 °C/hour	
Cooling capacity at 20 °C: 0.80 kW	Cooling capacity at 20 °C: 4.6 kW	Indicative performance rates for 250 liter bag holder:	
Pump pressure/suction max: 0.7/0.4 bar	Pump pressure max: 3.2 bar	Heating rate: 8 °C/hour (20 to 37 °C in 2 hours)	
Pump flow maximum pressure / suction: 25/23 L/min	Pump flow maximum pressure: 40 L/min	Cooling rate: 4 °C/hour	
Maximum bath volume: 8 L	Maximum bath volume: 18 L		
Overall dimensions (W x D x H): 285 x 430 x 688 mm	Overall dimensions (W x D x H): 550 x 650 x 970 mm		



Life Sciences

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