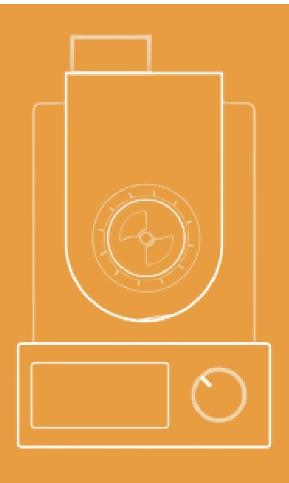


Vertical-Wheel®Bioreactor Product Guide

Accelerating Therapies From Start to Scale





A New Paradigm for Cell Therapy Process Development

The PBS single-use Vertical-Wheel® Bioreactor is a cutting-edge system engineered for the high-efficiency expansion of induced pluripotent stem cells (PSC), mesenchymal stem cells (MSC), CAR-T and NK cells and seamless process scale-up. Designed with Vertical-Wheel hydrodynamics, it creates an optimized culture environment that enhances cell growth, viability, and differentiation potential.

By **enabling early-stage process optimization** with direct scalability, the Vertical-Wheel platform significantly **reduces material costs, time, and labor**, helping researchers and biomanufacturers streamline workflows, minimize failure risks, and accelerate the development of **cell-based therapies**.



Compatible

Beneficial for the production of a variety of mammalian cell types.

Scalable

Commercially available in single-use vessel working volumes from 60mL to 80L.

Published

Featured in over 90+ peer reviewed scientific journal articles, worldwide.



A Look Inside the Vertical-Wheel Bioreactors

Vertical-Wheel Bioreactors are comprised of 3 subsystems:

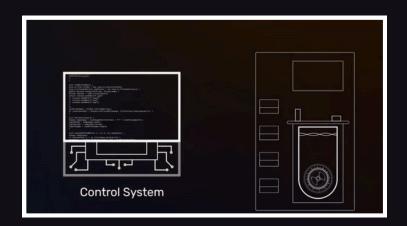


1. Disposable Vessel

Where the cell culture is grown.

2. Control System

The software that controls all aspects of the cell process.

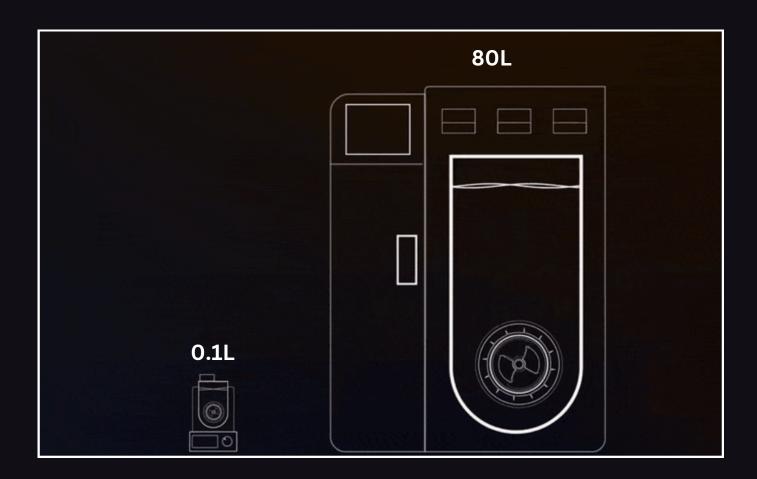


Electro-mechanical System

3. Electro-mechanical System Includes the sensor, pumps and the motor.

Designed to Effectively Scale-up Your Cell Therapy

Vertical-Wheel Bioreactors enable scalable manufacturing of allogeneic therapies derived from cells such as induced pluripotent stem cells, mesenchymal stem cells, and CAR-T or NK cells from 0.1L to 80L, empowering scientists to develop cell therapy products that combat cancer, diabetes, and heart failure.



60mL-100mL Working Volumes

The PBS-0.1 Mini Vertical-Wheel Bioreactor is compatible with 60mL-100mL working volumes and is the best starting point for early process development.



- Allows for sterile liquid handling in biosafety hoods
- Qualified for use in first-in-human clinical trials
- · Compatible with PBS Mini Base Unit

Part Numbers

Product Type	Product Description	Product Number
Base Unit	PBS-Mini Vertical-Wheel Bioreactor Base Unit (120-240 V)	<u>FA-UNI-B-501</u>
Single-Use Vessels	PBS-0.1 Vertical-Wheel Single-Use Vessel (pack of 4)	FA-0.1-D-001
Olligio-030 Vossois	PBS-0.1 Vertical-Wheel Single-Use Vessel with Bottom Port (pack of 1)	FA-0.1-D-101
Accessories	PBS-Mini Extended 4-Gang DC Power Distribution Cable	<u>IA-UNI-BA-112</u>

Specifications

Working volume range:	20 - 100 mL (For liquid mixing)60 - 100 mL (For cell culture)
Number of ports	1
Gassing	Diffusion through 0.22 micron filter on vent cap
iquid transfer	Port with screw-on vent cap
Product contact materials	Meet requirements for USP Class VI Testing for Plastics and/or ISO 10993

300mL-500mL Working Volumes

The PBS-0.5 Mini Vertical-Wheel Bioreactor is compatible with 300mL-500mL working volumes and is the best starting point for early process development.



- Allows for sterile liquid handling in biosafety hoods
- Qualified for use in first-in-human clinical trials
- · Compatible with PBS Mini Base Unit

Part Numbers

Product Type	Product Description	Product Number
Base Unit	PBS-Mini Vertical-Wheel Bioreactor Base Unit (120-240 V)	<u>FA-UNI-B-501</u>
Single-Use Vessels	PBS-0.5 Vertical-Wheel Single-Use Vessel (pack of 4)	FA-0.5-D-001
Olligie-Ose Vessels	PBS-0.5 Vertical-Wheel Single-Use Vessel with Bottom Port (pack of 1)	FA-0.5-D-101
Accessories	PBS-Mini Extended 4-Gang DC Power Distribution Cable	IA-UNI-BA-112

Specifications

Working volume range:	100 - 500 mL (For liquid mixing) 300 - 500 mL (For cell culture)
Number of ports	2
Gassing	Diffusion through 0.22 micron filter on vent cap
iquid transfer	Port with screw-on vent cap
Product contact materials	Meet requirements for USP Class VI Testing for Plastics and/or ISO 10993



The PBS Mini Bioreactor 90 Day Guarantee

If you are not satisfied with the performance of the PBS-Mini products or accessories get your money back. Must show necessary performance documentation to qualify.

1.8L-3L Working Volumes

The PBS-3 Vertical-Wheel Bioreactor is compatible with 1.8L-3L working volumes and enables bench-scale cell therapy process development.



- · Qualified for use in clinical trials
- Compatible with single-use DO and pH sensors
- Touchscreen interface for intuitive process customization, control, and reporting

Part Numbers

Product Type	Product Description	Product Number
Bioreactors	PBS-3 Vertical-Wheel Bioreactor, Single-Use Sensors (120 V)	<u>IA-3-B-701</u>
	PBS-3 Vertical-Wheel Bioreactor, Single-Use Sensors (240 V)	<u>IA-3-B-702</u>
	PBS-3 Vertical-Wheel Single-Use Vessel (Floored Wheel)	FA-3-D-504
Single-Use Vessels	PBS-3 Vertical-Wheel Single-Use Vessel (Floorless Wheel)	<u>FA-3-D-506</u>
	PBS-3 Vertical-Wheel Single-Use Vessel, Single-Use Sensors (Floored Wheel)	FA-3-D-704-L
	PBS-3 Vertical-Wheel Single-Use Vessel, Single-Use Sensors (Floorless Wheel)	FA-3-D-706-L
Accessories	PBS-3 Reusable Thermal Well	<u>IA-3-BA-006</u>
Accessories	PBS-3 Dip Tube Assembly	<u>IA-3-BA-007</u>

1.8L-3L Working Volumes

Part Numbers

Product Type	Product Description	Product Number
	PBS Autoclavable Pouch, 4" x 15" (pack of 2)	IA-UNI-DA-003
	PBS Single-Syringe Sampling Line, 20mL	IA-UNI-DA-006
Accessories	PBS Autoclavable Pouch, 8" x 18" (pack of 2)	IA-UNI-DA-007
7.0000001100	Reusable DO Sensor, 12mm OD x 220mm L with Right-Angle	<u>IC00468</u>
	Reusable pH Sensor, 12mm OD x 225mm L	<u>IC00469</u>
	60 Micron Plastic (PE) Retention Filters (pack of 5)	<u>IC01036</u>
Software	PBS-3 Vertical-Wheel Bioreactor Software 3.0 (21 CFR Part 11 cGMP Upgrade)	<u>IA-3-SW-001</u>
Qualification Packages	PBS-3 Vertical-Wheel Bioreactor IQ/OQ Protocols	IA-3-BQ-004
	PBS-3 Vertical-Wheel Bioreactor IQ/OQ Configuration Sheet	<u>IA-3-BQ-005</u>

1.8L-3L Working Volumes

Specifications

Working volume range:	1.8 – 3.0 L
Gas control	Mass flow controllers for air, N ₂ , O ₂ CO ₂
Vessel construction	Injection-molded polycarbonate vessel
Product contact materials	Meet requirements for USP Class VI Testing for Plastics <88> and/or ISO 10993



9L-15L Working Volumes

The PBS-15 Vertical-Wheel Bioreactor is compatible with 9L-15L working volumes and enables clinical and commercial manufacturing-scale cell therapy production.



Part Numbers

- Continue scale-up of process development or clinical stage production
- Compatible with single-use DO and pH sensors
- Adjustable height harvest valve (AHHV) allows for rapid medium exchange and harvesting

Product Type	Product Description	Product Number
	PBS-15 Vertical-Wheel Bioreactor (120 V)	<u>IA-15-B-501</u>
Bioreactors	PBS-15 Vertical-Wheel Bioreactor (240 V)	IA-15-B-502
	PBS-15 Vertical-Wheel Bioreactors, Single-Use Sensors (120 & 240 V)	<u>IA-15-B-701</u>
	PBS-15 Vertical-Wheel Single-Use Vessel (Floored Wheel)	IA-15-D-504-L
Single-Use Vessels	PBS-15 Vertical-Wheel Single-Use Vessel (Floorless Wheel)	<u>IA-15-D-506-L</u>
	PBS-15 Vertical-Wheel Single-Use Vessels, Single-Use Sensors (Floored Wheel)	IA-15-D-704-L
	PBS Autoclavable Probe Connector	IA-UNI-DA-001
Accessories	Reusable DO Sensor, 12mm OD x 220mm L with Right-Angle	IC00468
	Reusable pH Sensor, 12mm OD x 225mm L	<u>IC00469</u>

9L-15L Working Volumes

Part Numbers

Product Type	Product Description	Product Number
Software	PBS-3 Vertical-Wheel Bioreactor Software 3.0 (21 CFR Part 11 cGMP Upgrade)	IA-3-SW-001
Qualification	PBS-3 Vertical-Wheel Bioreactor IQ/OQ Protocols	<u>IA-3-BQ-004</u>
Packages	PBS-3 Vertical-Wheel Bioreactor IQ/OQ Configuration Sheet	<u>IA-3-BQ-005</u>

Specifications

Working volume range:	9 – 15 L
Gas control	Mass flow controllers for air, N ₂ , O ₂ , CO ₂
Vessel construction	Polyvinylidene Fluoride (PVDF)
Product contact materials	Meet requirements for USP Class VI Testing for Plastics <88> and/or ISO 10993



45L-80L Working Volumes

The PBS-80 single-use Vertical-Wheel Bioreactor is compatible with 45L-80L working volumes and enables large-scale single-use bioreactor enables commercial manufacturing-scale cell therapy production.



Part Numbers

- Expand clinical stage production or scale up into commercial scale manufacturing
- Touchscreen interface for intuitive process customization, control, and reporting
- Adjustable height harvest valve (AHHV) allows for rapid medium exchange and harvesting

Product Type	Product Description	Product Number
Bioreactors	PBS-80 Vertical-Wheel Bioreactor (120 V)	IA-80-B-511
Dioreactors	PBS-80 Vertical-Wheel Bioreactor (240 V)	<u>IA-80-B-512</u>
Single-Use Vessels	PBS-80 Vertical-Wheel Single-Use Vessel (Floored Wheel) [Legacy Product]	<u>IA-80-D-511-L</u>
	PBS-80 Vertical-Wheel Single-Use Vessel (Floored Wheel)	<u>IA-15-D-506-L</u>
	PBS Autoclavable Probe Connector	<u>IA-UNI-DA-001</u>
Accessories	Reusable DO Sensor, 12mm OD x 220mm L with Right-Angle	<u>IC00468</u>
	Reusable pH Sensor, 12mm OD x 225mm L	<u>IC00469</u>
Software	PBS-80 Vertical-Wheel Bioreactor Software 3.0 (21 CFR Part 11 cGMP Upgrade)	<u>IA-80-SW-001</u>

45L-80L Working Volumes

Specifications

Working volume range:	45 – 80L
Gas control	Mass flow controllers for air, N ₂ , O ₂ , CO ₂
Vessel construction	Polyvinylidene Fluoride (PVDF)
Product contact materials	Meet requirements for USP Class VI Testing for Plastics <88> and/or ISO 10993



The PBS Biotech Commitment to Quality and Cell Therapy GMP Manufacturing Readiness





Key Customer Benefits of ISO 9001:2015 Certification

- · Improved product and service quality: Consistent quality ensures customers receive products and services that consistently meets expectations. Products and services are built
- Confidence in reliability, robustness, and efficacy: ISO certification demonstrates PBSs' commitment to quality, assuring customers that they can rely on the products and services.
- Increased on-time delivery: ISO 9001 facilitates PBSs' efficiency, resulting in improved delivery times and accuracy.
- Reduced returns: By identifying and addressing potential quality issues proactively, fewer defective products reach customers, minimizing dissatisfaction.
- Better customer service and greater transparency: Framework to understand customer needs and expectations and seek feedback
- Continual improvement: PBS actively looks to enhance processes and quality, ensuring customers benefit from ongoing improvements.



We are cGMP Compliant

All Vertical-Wheel Single-Use Vessels and Bioreactors are manufactured under cGMP standards, ensuring strict control, thorough documentation, and consistent quality for safe and reliable cell & gene therapy production:

- Electronic Quality Management Systems
- Controlled Manufacturing Environment
- Validated Manufacturing Processes
- Robust Quality Control Procedures
- Detailed Documentation
- Calibrated Equipment
- Trained Personnel
- Risk Management
- Change Control

We Meet FDA 21 CFR Part 11

Vertical-Wheel Bioreactor software supports accurate data capture and tracking to maintain a trustworthy audit trail and comply with FDA regulations:

- Electronic Signatures
- Secure User Access
- Validation Protocols
- Data Integrity
- Audit Trail

