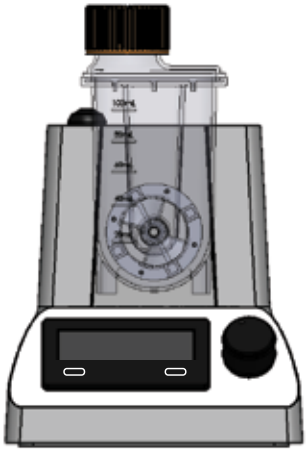
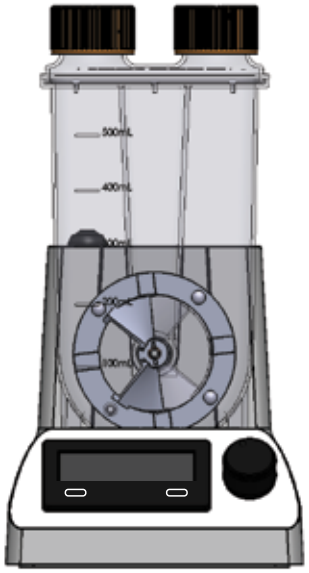
VERTICAL-WHEEL™
BIOREACTORS

PBS MINI



PBS 0.1 MAG



PBS 0.5 MAG

Single-Use Bioreactors with Vertical-Wheel™ Technology

User Manual

Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information

IDENTIFICATION OF PRODUCT: PBS-MINI

RESPONSIBLE PARTY: PBS Biotech, Inc.
4721 Calle Carga
Camarillo, CA, 93012 USA
1 (805) 482-7272

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at the user's own expense.

This device complies with / Cet appareil est conforme à la norme **Canada ICES-003 (A) / NMB-003 (A)**

PBS Biotech Inc.

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Safety

	If any PBS Biotech equipment is used in a manner not specified by PBS Biotech, the protection provided by the equipment may be impaired.
	The power cord is the main electrical disconnect for the unit. To remove power from the unit, unplug the power cord. Do not position the unit in such a way that it is difficult to unplug the power cord.
	To avoid damage or injury, only use power supplies and accessories provided by PBS Biotech. Only use vessels manufactured by PBS Biotech for the specific model of your bioreactor.
	Do not use the equipment in hazardous atmospheres or with hazardous materials for which the equipment is not designed.
	Biological substances such as viruses, cells, and sera, have the potential to transmit infectious diseases. If biohazardous materials are used with this device, follow all applicable local, state/provincial, and/or national regulations, including identification of samples with the biohazard symbol. Wear appropriate protective eyewear, clothing, and gloves.
	If the equipment has been used in a biohazardous environment, it must be decontaminated according to all applicable local, state/provincial, and/or national regulations prior to any shipment or disposal.

About the PBS MINI

The PBS MINI Bioreactor System is a single-use cell culturing device, intended primarily for culture of mammalian cells in therapeutic protein, vaccine, gene therapy, and cell therapy applications. This system consists of a MINI Single-Use Vessel with the patented Vertical-Wheel™ Impeller and a non-disposable MINI Universal Base Unit that holds the vessel. The Base Unit can accommodate either a PBS 0.1 Single-Use Vessel or a PBS 0.5 Single-Use Vessel.

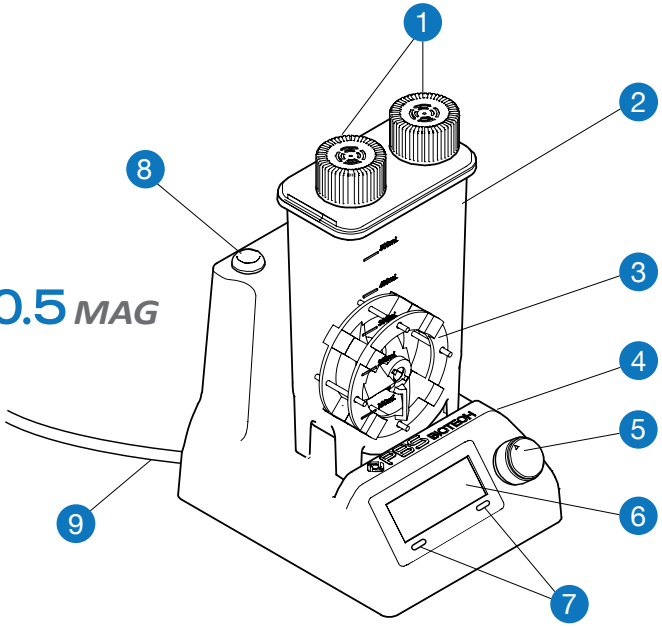
The MINI Bioreactor Base Unit is comprised of a stainless steel chassis and base, with an injection-molded plastic enclosure. The entire Base Unit is environmentally sealed for use in up to 100% humidity (condensing) conditions and is constructed to be cleanable with 70% isopropyl alcohol, or equivalent. The Base Unit may be powered by an AC power source at 100-120 VAC or 200-240 VAC using the included power adapter.

The PBS 0.1 and PBS 0.5 Single-Use Vessels are primarily constructed from injection-molded polycarbonate and are sterilized by gamma radiation to be ready-for-use by the customer. All product-contact surfaces in the Single-Use Vessels consist of components certified to be Animal-Derived Component Free (ADCF) and compliant to USP Class VI, ISO 10993, or equivalent.

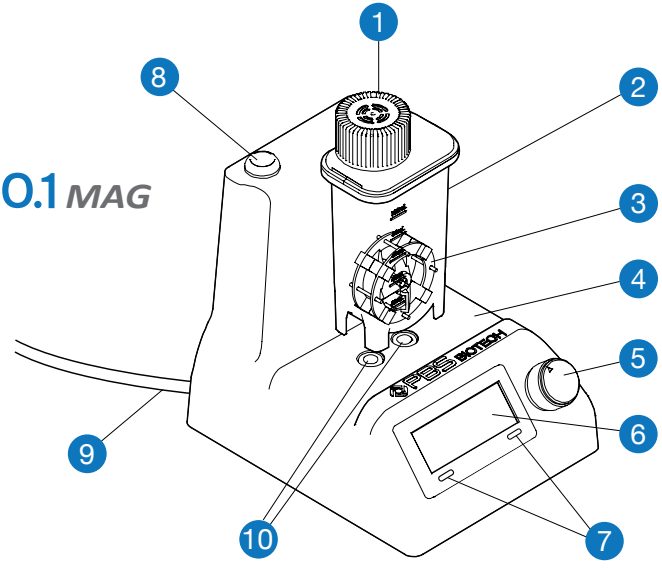
The agitation rate in the Single-Use Vessel is controlled by the speed adjust dial on the MINI Bioreactor Base Unit and is displayed on the digital speed display next to the dial. To regulate temperature, pH, and dissolved oxygen (DO) levels in the culture, the system must be placed in a warm room or an incubator with appropriate temperature and gas controls.

PBS MINI at a Glance

PBS 0.5 MAG



PBS 0.1 MAG



1 **Vent Cap(s)**
Contains a 0.22 micron sterilizing-grade filter membrane for gas exchange. Can be removed from the Single-Use Vessel for liquid handling.

2 **PBS Single-Use Vessels (0.1 L or 0.5 L)**
Contains and mixes up to 100 mL or 500 mL of cell culture at a controlled speed with the integrated Vertical-Wheel™ Impeller.

3 **Vertical-Wheel™ Impeller**
Rotates vertically inside the Single-Use Vessel to facilitate efficient mixing, in combination with the unique shape of the bioreactor vessel.

4 **Universal Base Unit**
Provides agitation power and illumination to either Single-Use Vessel size.

5 **Speed Adjust Dial**
Allows variable control of the Vertical-Wheel™ Impeller's rotation, with rated speed from 5 to 100 RPM. Turns impeller rotation on/off, as indicated by a click sensation and sound.

6 **Digital Speed Display**
Indicates the speed set point (to the nearest RPM) selected by the dial.

7 **SEL & RST Buttons**
Reserved for factory setup and programming. No effect on function of PBS MINI.

8 **LED Light Power Button**
Turns the LED lights on or off.

9 **External DC Power Cord**
Supplies power to the Base Unit from an A/C power source. The power supply on the cord should be kept outside of the incubator by running the thin DC extension cable through the incubator door seal.

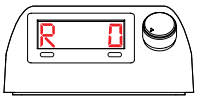
10 **White LED Lights**
Offer enhanced visualization of microcarrier suspension and cell culture in the Single-Use Vessel. (Not pictured on the PBS 0.5 MINI; located underneath the vessel).

Technical Highlights for PBS MINI

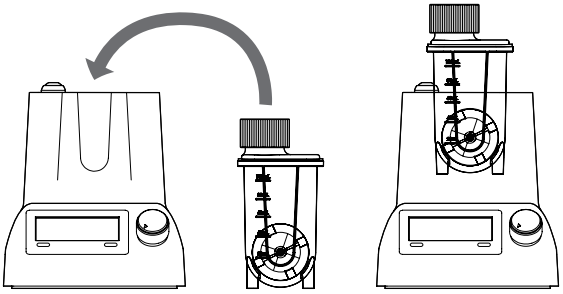
FEATURES	PBS 0.1 MAG	PBS 0.5 MAG
Universal Base Unit		
Size: • Width • Depth • Height • Weight	5.3 in (13.5 cm) 7.3 in (18.5 cm) 6.1 in (15.5 cm) 2.8 lb (1.3 kg)	
Vertical-Wheel™ agitation: • Mechanism • Speed range • Speed control • Display	Magnetic coupling 5 -100 RPM Speed Adjust Dial controls on/off and agitation rate Digital display of agitation (RPM)	
Operational ranges: • Temperature • Humidity • Altitude • Environment	16 °C to 40 °C 5% to 100% (condensing) Up to 2,000 m Indoor use, pollution degree 2	
Electrical: • Power supply • Base unit	Input: 1 A MAX, 100 - 240 V~, 50 - 60 Hz, CI. II Output: 1.5 A, 24 Vdc (LPS) Input: 24 Vdc ⎓ 120 mA	
Safety and regulatory	NRTL, CE	
Construction	Stainless steel chassis & base, injection-molded plastic enclosure, environmentally sealed components	
Illumination of vessel	Two embedded white LEDs	
Single-Use Vessel		
Size: • Width • Depth • Height • Height (vessel on base)	 2.5 in (6.4 cm) 1.8 in (4.6 cm) 5.0 in (12.8 cm) 8.0 in (20.2 cm)	 4.0 in (10.2 cm) 2.4 in (6.2 cm) 8.0 in (20.2 cm) 10.1 in (25.6 cm)
Working volume range: • For liquid mixing • For cell culture	 20 – 100 mL 60 – 100 mL	 100 – 500 mL 300 – 500 mL
Number of ports	1	2
Gassing	Diffusion through 0.22 micron filter on vent cap	
Liquid transfer	Port with screw-on vent cap	
Product contact materials	Meet requirements for USP Class VI Testing for Plastics <88> and/or ISO 10993	

Installing the PBS MINI

1. Place a PBS MINI Bioreactor Base Unit in an incubator or in a warm room and route the extension cable to a convenient location.
2. Make the connection between the extension cable and power supply outside of the incubator. Plug the power supply in to an electrical outlet.
3. Add cell culture medium or other applicable solution into a PBS 0.1 or PBS 0.5 Single-Use Vessel by removing the Vent Cap. Perform this operation in a biosafety cabinet or other controlled environment to maintain sterility in the Single-Use Vessel.
4. Confirm the Speed Adjust Dial on the Base Unit is set to 0 RPM.

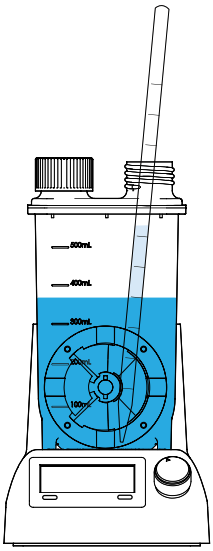


5. Install the Single-Use Vessel in the Base Unit by matching the back of the Vessel with the dovetail groove on the Base Unit and sliding it down the groove. Note that there will be a sizeable vertical gap between the bottom of the PBS 0.1 Single-Use Vessel and the Base Unit even when it is installed properly.



6. Turn the Speed Adjust Dial to set the agitation rate in the Vessel to desired speed.
7. Turn on the LED lights to visualize the Vertical-Wheel™ Impeller rotation, as needed. The LEDs should be turned off whenever possible when working with a light-sensitive process.

Removing a Sample from the PBS MINI



- To keep the cells evenly mixed during sampling, a Base Unit should be used in the biosafety cabinet to control agitation rate.
- To remove sample from the very bottom of the vessel, the Vertical-Wheel™ Impeller must be rotated so the vanes are at the top and bottom of the wheel, as illustrated.

Maintenance and Cleaning

- The only required maintenance is to regularly clean the Base Unit with a solution of 70% isopropyl alcohol, or equivalent.
- The Base Unit has no user-serviceable parts. Do not attempt to disassemble the Base Unit.

Troubleshooting the PBS MINI

Issue with Powering Up

1. Verify that the Base Unit is plugged into a functional electrical outlet. Unplug the Base Unit from the outlet and re-plug it into the outlet.
2. If you are using a power strip or a surge protector, verify that its switch is also turned on.
3. Verify the cable on the external power supply is securely connected.

Issues with Agitation

Note: The display gets updates from the motor several times per revolution. This may result in the displayed rotational speed oscillating between a few RPM.

1. Verify that the Base Unit is powered up properly.
2. Verify that the Single-Use Vessel sits all the way down in the Base Unit to ensure proper magnetic coupling.
3. Verify that the Speed Adjust Dial is not in the off position.
4. Visually determine any faults in the Vertical-Wheel™ Impeller:
    - Is there any visible damage to the impeller?
    - Does the impeller rotate smoothly in its bearings?

Issues with LED Lights

1. Verify that the Base Unit is powered up properly.
2. Push down firmly on the LED Light Power Button.

For further questions, please contact Customer Service at customer.service@pbsbiotech.com.

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