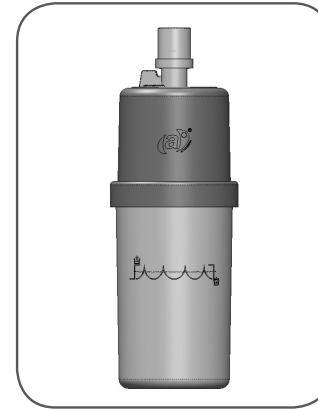


# Babi.Plus™

## Bubble PAP Valve 0 – 10cm H<sub>2</sub>O



REF BC01



### INDICATIONS:

The *Babi.Plus*™ Bubble PAP Valve is a single patient use positive end expiratory pressure valve for use with infant patients weighing < 10 Kg in hospital environments to increase end lung pressure above atmospheric in constant flow conditions.

### CONTRAINDICATIONS:

Contraindicated in individuals not requiring elevated lung pressure therapy.

### APPLICATION:

The *Babi.Plus*™ Bubble PAP Valve is installed at the end of an expiratory limb in a continuous gas flow system to provide back pressure within the system.

### ⚠ WARNINGS:

- PAP therapy may have an adverse effect on cardiopulmonary status.
- Always monitor, maintain and verify PAP level with a manometer that measures proximal airway pressure.
- Read and understand the contents of this insert and demonstrate proficiency in the application of this device prior to use.
- The product is intended to be used by qualified medical personnel trained in pulmonary ventilation and advanced cardiac life-support techniques.
- This PAP Valve has not been tested for use during Magnetic Resonance Imaging (MRI). However, this device does not contain any ferrous material. The use of the PAP Valve during MRI procedures may result in the failure of the device, blurring of the image, or misinterpretation of the image.
- Do not attempt to disassemble the Valve as it will damage the components.
- Single-patient use, do not reuse, soak, rinse, or sterilize PAP Valve with chemicals as these procedures may leave harmful residues and may impede the function of the PAP Valve.

### ⚠ CAUTIONS:

- Evaporation or condensation of water may occur during operation of this device. Always monitor water level and adjust as required.
- Use of this device at gas flow rates of greater than 12 LPM may result in higher end expiratory pressures being delivered.

## INSTRUCTIONS FOR USE:

- Prior to use on a patient, read these instructions, warnings, cautions and demonstrate proficiency in the use of this device to deliver PAP therapy.
- Inspect the device for damage, discard if present.

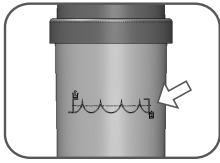


fig. 1

- To fill the water reservoir (fig. 1):
  - Remove the lid from the jar.
  - Fill the jar to the mean fill line with sterile water.

**Note: b.1.** To assure consistency, water level must be between minimum and maximum lines without the drop tube beneath the surface of the water.

**Note: b.2.** The PAP Valve reference marks indicate PAP level at the mean water line at 6 LPM.

- Replace the lid on to the jar.

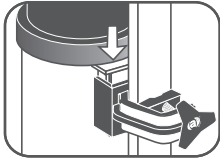


fig. 2

- To attach the PAP (fig. 2) Valve to a mounting clamp, simply slide the equipment mount into the corresponding equipment mount holder. Use of this type of mounting system will assure that the device remains in the upright (vertical) position.

**Note:** This device includes an integral equipment mount that is intended to mate with an ISO 19054:2005(E) compliant equipment mount holder.

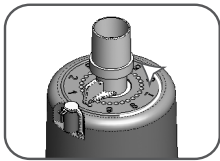


fig. 3

- Set the device to the minimum position by rotating the PAP Adjustment lever to the full anticlockwise position (fig. 3).

- Adjust the gas flow to the desired level and connect the expiratory end of the breathing circuit to the gas inlet connector.

**CAUTION:** Use of this device at gas flow rates of greater than 12 LPM may result in higher end expiratory pressures being delivered.

- Using clockwise rotation, adjust the device to the desired back pressure [Positive Airway Pressure (PAP)] level (fig. 4).

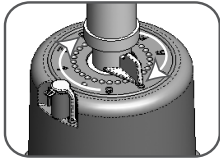


fig. 4

- During use, continuously monitor airway pressure with an accurate pressure monitoring device and adjust the device accordingly (fig. 5).

**WARNING:** Always monitor, maintain and verify PAP level with a manometer that measures proximal airway pressure.

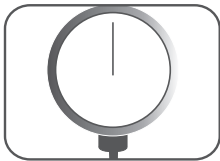


fig. 5

- A water level adjustment port (fig. 6) is provided to adjust water level without interruption of therapy. To use, remove the luer cap and connect a syringe to the port, adding or removing water as required.

**CAUTION:** Evaporation or condensation of water may occur during operation of this device. Always monitor water level and adjust as required.

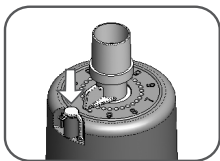


fig. 6

- Discard after use. Do not reuse this product.

**WARNING:** Single-patient use, do not reuse, soak, rinse, or sterilize PAP Valve with chemicals as these procedures may leave harmful residues and may impede the function of the PAP Valve.

## MAJOR COMPONENTS AND INDICATORS:

ITEM	DESCRIPTION	
	A	15 mm x 22 mm Gas Inlet
B	Lid	
C	Water Level Line	
D	Jar	
E	Water Level Adjustment Port	
F	Expiratory Gas Ports	
G	Equipment Mount	
H	PAP Adjustment Lever	
I	PAP Reference Marks	

SPECIFICATIONS:	
Connector	ISO-5356-1:2004 compliant 15 mm x 22 mm, 360° single plane swivel connector
Pressure range	0 - 10 cm H <sub>2</sub> O
Accuracy	± 1.0 cm H <sub>2</sub> O
Gas flow range	1 to 12 LPM
Material	Polypropylene, polyethylene and silicone rubber
Operating temperature	10°C to 44°C (50°F to 111°F)
Storage temperature	-40°C to 60°C (10°F to 140°F)

## ORDERING INFORMATION:

Product Code	Description	Qty
BC01	Babi.Plus™ Bubble PAP Valve 0- 10 cm H <sub>2</sub> O	12 to case
C101	A Plus Pole Clamp	1 to box



Designed by A Plus Medical, U.S.A.  
**A Plus Medical**  
 www.aplus-medical.com  
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Product structure and/or specification subject to change without prior notice.  
 U.S. Patent 7077154 and other Patents Pending