

B&B Bubbler™

Water Seal CPAP Valve

0-10 cm H₂O

Contents: 1 UNIT

LOT

REF 25312

Not Made With Natural Rubber Latex

Caution: Federal law restricts this device to sale by or on order of a physician.

Storage Temperature:
-40°C to 60°C (10°F to 140°F)



Packaged Clean
— Not Sterile —



— Disposable —
Single Patient Use Only
DO NOT REUSE

Manufactured for:
B&B Medical Technologies
1954 Kellogg Ave. Ste 100
Carlsbad, CA 92008 U.S.A
Phone: +1.760.929.9972
Fax: +1.760.929.9953
www.BandB-Medical.com

By: AOK TOOLING LIMITED
Kowloon, Hong Kong

Patent Pending. Made in China.
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Form: S253U Rev 1.1



READ AND UNDERSTAND COMPLETE INSTRUCTIONS PRIOR TO USE

INDICATIONS:

The B&B Bubbler is intended to provide CPAP, in a hospital environment, to spontaneously breathing neonates and infants < 10 kg who require breathing support due to conditions associated with prematurity or other conditions where CPAP is required or desired and is prescribed by a physician.

CAUTIONS:

The B&B Bubbler is intended to be used by qualified medical personal trained in oxygen delivery, ventilation, cardiopulmonary monitoring, and assessment of the newborn.

Evaporation or condensation of water may occur during operation of this device. Frequent monitoring of the water level is required to assure consistent delivery of set pressure.



Single patient use. Re-use on multiple patients may degrade the performance of the product and/or cause cross contamination.

CONTRAINDICATIONS:

Contraindicated in patients not requiring elevated lung pressure therapy.

WARNINGS:

CPAP therapy may have an adverse effect on the cardiopulmonary status of the patient and must be prescribed by a licensed physician.

Use of this device at gas flow rates greater than 12 LPM is not recommended and may result in the delivery of higher pressures than what is set.

Always monitor, maintain and verify the CPAP level with a manometer that measures proximal airway pressure.

READ AND UNDERSTAND COMPLETE INSTRUCTIONS PRIOR TO USE.

AFTER PATIENT USE: Discard the B&B Bubbler after single patient use. Do not re-use, soak, or sterilize the B&B Bubbler.

INSTRUCTIONS:

1. Inspect the device for damage and discard if damaged.
2. Fill the water reservoir to the solid fill line with sterile water or sterile 0.25% acetic acid solution (Refer to F and J). Add water to the bubbler through either the gas inlet adapter, located in the center of the bubbler, or by instilling water through the water level fill port, adjacent to the inlet port (Refer to H and B).
3. Slide the B&B Bubbler into a 30 mm pole or rail-mount bracket to assure that the device remains in an upright position using the equipment mount located on the rear side of the B&B Bubbler (Refer to I).

PRIOR TO PATIENT APPLICATION:

- While holding the CPAP Dial (Refer to C), press the Setting Lock Button (Refer to D) and rotate the CPAP dial counterclockwise to align the red arrow with the prescribed correlating CPAP level on the B&B Bubbler (Refer to G & A). Release the Setting Lock Button to lock the CPAP dial in place.
- Adjust the air/oxygen blended gas flow to the desired level between 1-12 LPM.
- Connect the expiratory end of the breathing circuit to the gas inlet connector (Refer to H) of the B&B Bubbler.
- Connect an airway pressure manometer to the circuit between the patient interface and the inspiratory side of the circuit.

- Connect a pressure relief manifold between the blended gas supply and the inlet port of a humidifier. The pressure relief manifold will limit the delivered pressure in the event of an occlusion.
- Before attaching the interface to a patient, occlude the patient interface connected to the circuit and confirm the desired pressure setting. Assure bubbling is visible and check the integrity of the breathing circuit.

DURING PATIENT APPLICATION:

- Continuously monitor the pressure delivered through the circuit with the use of the manometer. While holding the CPAP dial, adjust it accordingly by pressing on the Setting Lock Button and rotating the CPAP dial to deliver the physician-ordered CPAP.
- Monitor and adjust the water level to assure consistent delivery of CPAP. Monitor the water level by inspecting both the solid fill line (Refer to F) and the internal overflow chamber. To add water remove the plug on the water level fill port (Refer to B). While holding the CPAP Dial, connect a syringe to the port and add water as needed. Excess water will automatically flow into the overflow chamber. If water is in the overflow chamber, drain the water by removing the drain plug (Refer to E), located on the bottom of the B&B Bubbler. Reattach the plug when empty.
- Replace the B&B Bubbler as needed and in accordance to hospital infection control recommendations.

SPECIFICATIONS AND OPERATION:

The B&B Bubbler has an internal overflow chamber which limits the water level to the targeted and desired height throughout the course of therapy. External ports enable the user to drain water in the overflow chamber and add water to the system without disengaging the device, allowing the B&B Bubbler to remain a closed system.

The B&B Bubbler is a double walled vessel. The inner vessel controls the CPAP level. There is a small passage which opens to the outer vessel where the oscillations of the bubbling of water is dampened. The mean water level can be accurately read in the outer vessel without interrupting the delivery of CPAP to the patient.

SPECIFICATIONS:

Connector: ISO 5356-1:2004 compliant
15 mm x 22 mm, 360° single plane swivel connector

Pressure: Range 0 – 10 cm H₂O

Accuracy: ± 1.0 cm H₂O

Gas Flow Range: 1 to 12 LPM

Material: Polypropylene and ABS

Operating Temperature: 10°C to 40°C (50°F to 104°F)

Storage Temperature: -40°C to 60°C (10°F to 140°F)

