

SMART BAG[®]

SILICONE BAG-VALVE-MASK RESUSCITATOR

"THE MOST REVOLUTIONARY ADVANCE IN BVM DESIGN FOR OVER 40 YEARS!"



The SMART BAG[®] Silicone Reusable Bag Valve Mask Resuscitator is a reusable device for manual ventilation. The SMART BAG[®] offers accurate controlled ventilation that significantly reduces the risk of gastric insufflation. The patient's airway pressure is maintained at an optimally low level due to the SMART[®] technology in the bag that responds to both the rescuer's squeeze of the bag and the patient's own respiratory condition. It is designed for use in various clinical settings to provide respiratory support to the respiratory distressed or non-breathing patient.

The Child resuscitator comes standard with a Pressure Relief Valve set at 40 cm H₂O which can be overridden by the operator. A pressure relief system, set at either 40 cm H₂O or 60 cm H₂O, is available for the Adult resuscitator. When used with a supplemental oxygen supply, the device may provide 100% oxygen on every squeeze of the bag.

PREPARATION FOR USE:

1. Inspect the SMART BAG[®] resuscitator to ensure that all components are present and properly assembled.
2. Test for leaks by occluding the patient port completely squeezing the bag (Any leaks in the system may prevent the delivery of a sufficient volume to the patient).
3. Squeeze and release the SMART BAG[®] hard a few times to ensure that air is moving through the valve system to the mask. The SMART[®] Valve in the neck of the bag should move freely indicating increased airway pressure and you should notice an immediate increase in bag tension (stiffness).
4. Gently squeeze and release the SMART BAG[®] a few times to ensure that the bag tension is reduced and the SMART[®] Valve in the neck of the bag does not move forward when you gently

squeeze. This provides confirmation that the airway pressure will be kept to the minimum required for adequate ventilation to occur while reducing the risk of gastric insufflation.

5. If using supplemental oxygen, attach the reservoir system to the bag refill port and ensure that the oxygen tubing is attached to an oxygen source with a flow rate of at least 15 L/min. Ensure that the collapsible reservoir system is fully extended to allow maximum oxygen storage.

DIRECTIONS FOR USE:

1. Select the appropriate SMART BAG[®] resuscitator model for the size of patient to be ventilated.
2. Ensure that the patient's airway is clear of any obstructions and remains open by properly positioning the patient's head in accordance with local protocols.
3. Maintain a proper mask-to-face seal with one hand by lifting the chin upward with the last three fingers of the hand. Keep the index finger and thumb on top of the mask to form a tight seal around the patient's mouth and nose.
4. Gently squeeze the SMART BAG[®] with the other hand until the chest rises, then release. Ventilate the patient with a steady squeeze and release of the SMART BAG[®] sufficient time between ventilations to allow for full emptying of the patient's lungs.
5. If the child SMART BAG[®] is being used and the Pressure Relief override is required to be applied, depress the Pressure Relief Button and rotate 90° to lock in place. To unlock simply rotate the button until the arrow lines up with the arrow on the patient valve and release.

**WARNING**

The SMART BAG® Silicone Reusable Bag Valve Mask Resuscitator should only be used by personnel trained in Cardio Pulmonary Resuscitation and in the use of this device.

Use only as directed. Improper use or Unauthorized modification of this product may result in user or patient injury.

Oxygen concentration (%) delivered by Adult SMART BAG® Resuscitator (values in parentheses are without an oxygen reservoir)						
O ₂ Input l/min	Tidal Volume (ml) x Ventilation Frequency (BPM)					
	600 x 12	600 x 20	750 x 12	750 x 20	1000 x 12	1000 x 20
5	82 (32)	58 (34)	65 (34)	50 (30)	55 (31)	45 (31)
10	97 (37)	80 (38)	97 (37)	97 (36)	88 (36)	62 (36)
15	99 (46)	97 (45)	99 (46)	99 (44)	97 (44)	90 (46)

Oxygen concentration (%) delivered by Child SMART BAG® Resuscitator (values in parentheses are without an oxygen reservoir)			
O ₂ Input l/min	Tidal Volume (ml) x Ventilation Frequency (BPM)		
	70 x 30	200 x 30	300 x 30
5	96 (66)	59 (38)	45 (33)
10	97 (82)	97 (48)	69 (38)
15	97 (89)	97 (48)	97 (48)

CLEANING METHODS:

1. Disassemble all parts for Cleaning. Do not attempt to disassemble the SMART BAG® Piston and Pressure Relief Valve Assembly (where applicable), as they can be easily cleaned without disassembly.

2. Wash parts thoroughly in warm water using a mild detergent. Ensure that the detergent is compatible with resuscitation equipment.

3. Rinse all parts thoroughly in clean water to remove all traces of the detergent.

DISINFECTION METHODS:

1. Automatic washing machine designed for disinfecting medical accessories by heating can be used for the parts.

2. Boiling: Immerse the parts in clean tap water, heat to boiling and kept for 10 minutes for disinfection.

3. Cydex or 10% bleach liquid can be used on all parts except reservoir. After exposing the parts to the chemical disinfectant, rinse all parts thoroughly in clean water to remove the residues.

STERILIZATION METHODS:

1. The parts may be sterilized by immersing in a legally marketed cold chemical sterilizing solution, autoclaving (Max 134°C, 274°F) or ethylene oxide gas. (**NOTE:** The reservoir bag should not be sterilizing by autoclaving)

2. Inspect all components for wear and re-assemble the resuscitator replacing any parts as deemed necessary.

3. Test the function of the re-assembled resuscitator prior to use.

Recommended sterilizing timing: First use of the new resuscitator, when patient is changed or when the same patient uses more than 48 hours.

Restriction on the number of reuses:

Reusable SMART BAG® manual resuscitators may be disinfected/ sterilized at least 30 times. Discontinue use and discard the SMART BAG® should material discoloration/ deterioration be observed.

SPECIFICATIONS:

Storage Temperature Range:	-40°C to 60°C / -40°F to 140°F	
Operating Temperature Range:	-18°C to 50°C / 0°F to 122°F	
Reservoir volume:	2700 ml	
Inspiratory Resistance:	3,3 cm H ₂ O	
Expiratory Resistance:	2,2 cm H ₂ O	
Patient Valve Dead space:	7,0 ml	
Bag Volume:	Adult: 1.700 ml	Child: 470 ml
Stroke Volume:	Adult: 900 ml	Child: 250 ml
Maximum Cycle Rate:	Adult: 45 bpm	Child: 100 bpm
Pressure Relief:	Adult - optional: 40 or 60 cm H ₂ O	Child: 40 cm H ₂ O

ORDERING INFORMATIONS:

O1BM3100	Silicone Reusable SMART BAG® (Adult) c/w Facemask and Reservoir System
O1BM3110	Silicone Reusable SMART BAG® (Child) c/w Facemask and Reservoir System



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