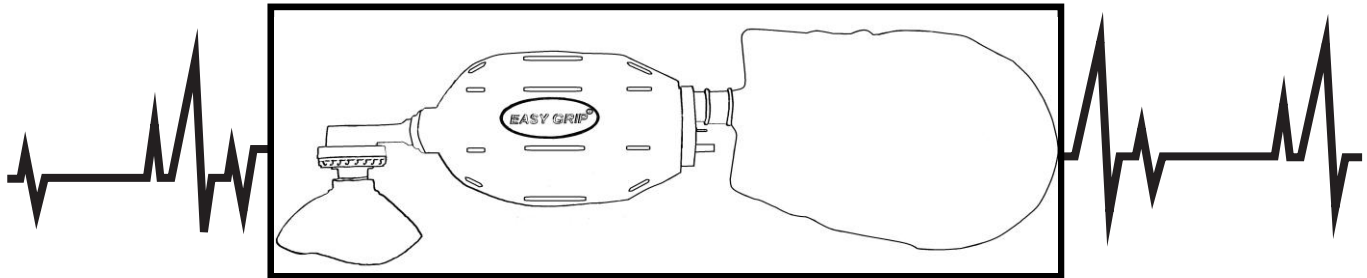


EASY GRIP[®]

Silicone Autoclavable Bag-Valve-Mask Resuscitator



The EASY GRIP[®] Silicone Bag Valve Mask Resuscitator is a reusable device for manual ventilation. It is designed for use in various clinical settings to provide respiratory support to the respiratory distressed or non-breathing patient.

The Child and Infant resuscitators come standard with a Pressure Relief Valve set at 40 cm H₂O which can be overridden by the operator. (This is optional on the Adult resuscitator).

When used with a supplemental oxygen supply, the device may provide 100% oxygen on every squeeze of the bag.

I. Preparation for use

1. Inspect the EASY GRIP[®] 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 EASY GRIP[®] hard a few times to ensure that air is moving through the valve system to the mask.
4. 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.

II. Directions for use:

1. Select the appropriate EASY GRIP[®] 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

patient with a steady squeeze and release of the EASY GRIP[®] sufficient time between ventilations to allow for full emptying of the patient's lungs.

5. If the child or infant EASY GRIP[®] 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.

6. Supplementary oxygen can be administered by connecting oxygen tubing to a flow oxygen source, with or without reservoir bag attachment. Oxygen concentration obtained under different tidal volume and ventilation frequency is displayed in the following charts (values in parentheses are without an oxygen reservoir):

Warnings:

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

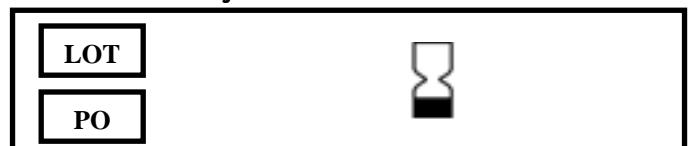
Use only as directed. Improper use or Unauthorized modification of this product may result in user or patient injury.

Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician.

ORDERING INFORMATION

- 01BM3600 EASY GRIP[®] Silicone Reusable (Adult) c/w Facemask and Reservoir System
- 01BM3610 EASY GRIP[®] Silicone Reusable (Child) c/w Facemask and Reservoir System
- 01BM3620 EASY GRIP[®] Silicone Reusable (Infant) c/w Facemask and Reservoir System



Oxygen concentration (%) delivered by Adult EASY GRIP® Resuscitator						
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	
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 EASY GRIP® Resuscitator			
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)

Oxygen concentration (%) delivered by Infant EASY GRIP® Resuscitator				
O ₂ Input l/min	Tidal Volume (ml) x Ventilation Frequency (BPM)			
	20 X 30	20 X 60	40 X 60	70 X 60
5	97 (75)	97 (72)	97 (59)	85 (52)
10	97 (75)	97 (78)	97 (78)	85 (61)
15	97 (95)	97 (92)	97 (82)	97 (73)

III. Cleaning, Disinfection and Sterilization

Parts exposed to expiratory gases (Patient Valve) shall be cleaned, disinfected or sterilized after each use. The rest of the parts shall be cleaned disinfected or sterilized as needed.

The whole set of the resuscitator shall be cleaned, disinfected or sterilized if it is used for patients or environments with infectious diseases.

The resuscitator shall be disassembled for cleaning, disinfection and sterilization except for the Pressure Relief Valve Assembly (where applicable), as it can be easily cleaned without disassembly.

After cleaning, disinfection or sterilization, inspect all components for wear and re-assemble the resuscitator replacing any parts as deemed necessary. Test the function of the re-assembled resuscitator prior to use as per section I-Preparation for use.

Cleaning methods:

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

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

SPECIFICATION:

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)
Patient Valve Dead space: 7.0 ml

Inspiratory Resistance: 3.3cm H₂O
Expiratory Resistance: 2.2cm H₂O

	Adult	Child	Infant
Bag Volume:	1700 ml	470 ml	300 ml
Stroke Volume:	900 ml	250 ml	130 ml
Maximum Cycle Rate:	45 BPM	100 BPM	95 BPM
Pressure Relief:		40 cmH ₂ O	40 cmH ₂ O
Reservoir Volume:	2500 ml	2500 ml	1000 ml


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