THE BAG II

Manual Single-Use Self-Inflating Resuscitator

DIRECTIONS FOR USE

REF

- ☐ Cat. no. 845011 Qty 1 The BAG Disposable Resuscitator, Adult w/Mask #5
- ☐ Cat. no. 845021 Qty 1 The BAG Disposable Resuscitator, Child w/Mask #3
- ☐ Cat. no. 845031 Qty 1 The BAG Disposable Resuscitator, Infant w/Mask #1
- ☐ Cat.no. 845041 Qty 1 The BAG Disposable Resuscitator, Adult w/Mask #4

(Shipped in cartons of 12 each)

LOT

CE 0434

LATEX FREE

Caution: Rx only.

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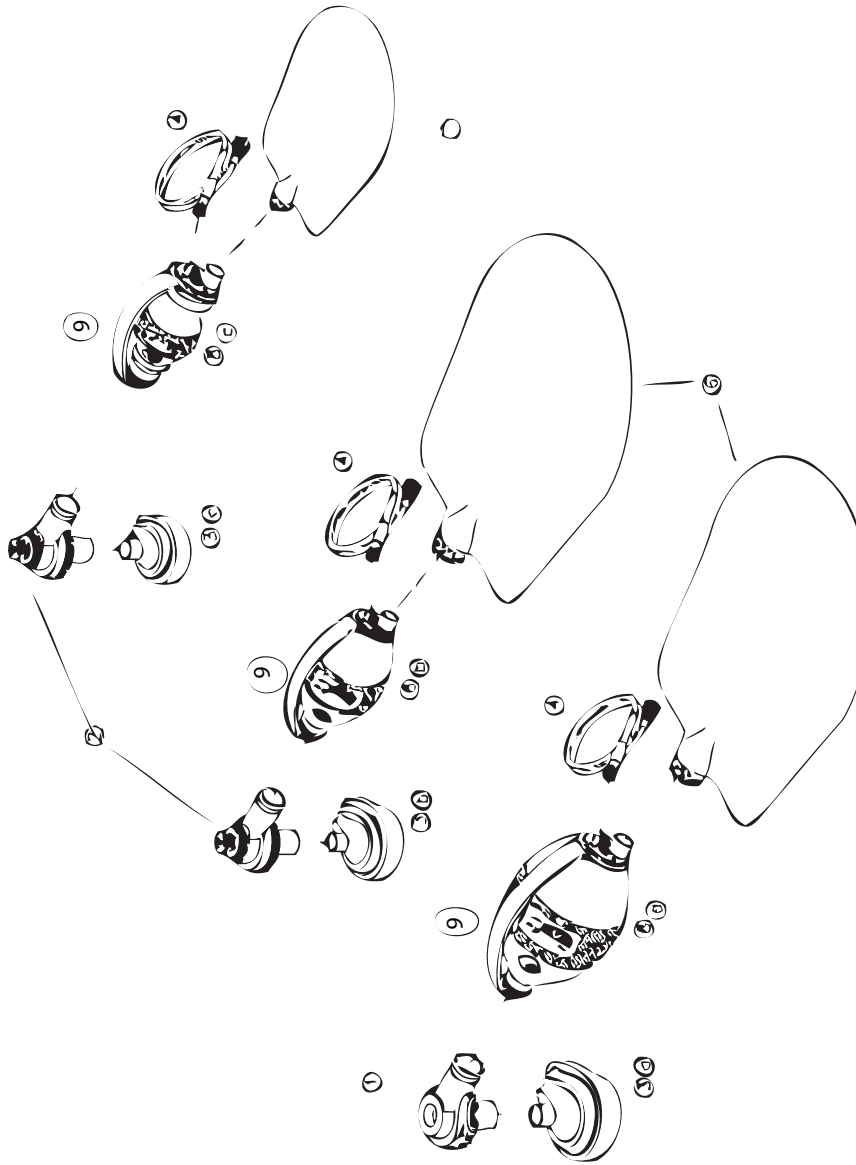
RevB

Figure 1. The BAG configurations and parts.



Indications for Use
The BAG resuscitator is a self-inflating, manual resuscitator that is intended for patients requiring total or intermittent ventilation support. The BAG resuscitator provides positive pressure ventilation and also allows for spontaneous breathing either with an artificial airway or with a face mask (3)(a), (b) or (c).

Cautions and Warnings
- Resuscitators should only be used by persons who have received specific training in their use.
- When using supplemental oxygen, do not allow smoking or use unit near sparking equipment, open flame, oil or other flammable chemicals.
- The BAG should not be used in toxic or hazardous atmospheres.
- Infant and Child units are equipped with a pressure-limiting device (2) which opens at a pressure of approx. 35±5 cmH_2O. However, an abrupt, high-volume manual breath may cause the unit to exceed this level. The pressure relief valve can be overridden by depressing the plunger momentarily with light finger pressure or locked in place by using the push-twist locking feature.
- The resuscitator is for single patient use only. Do not reuse. Do not sterilize.
- Use the appropriate resuscitator size (8)(a), (b) or (c). The wrong size can result in inadequate or excessive air pressure being delivered to the patient. See the Performance and Specifications table for sizing.
- When using supplemental oxygen, the flow from its source should be monitored. Delivery of supplemental oxygen greater than 30 LPM (Liters Per Minute) may result in inadvertent positive end expiratory pressure (PEEP).
- The use of third party products and oxygen delivery devices (e.g. filters and demand valves) with The BAG Disposable Resuscitator may have an affect on product performance. Please consult with the manufacturer of the third party device to verify compatibility with The BAG and obtain information on the possible performance changes.

Limited Warranty
The BAG Disposable Resuscitator is warranted against defects in workmanship and materials only. Please refer to the Global Warranty statement for additional terms and conditions (www.laerdal.com).

Practical Operation
1. Remove the resuscitator from the outer protective poly bag. Expand the Adult or Child resuscitator from collapsed configuration to its operating position.
2. Inspect the unit to be sure the system is complete.
3. **PRE-OPERATIVE FUNCTIONAL TEST:**
- Compress the ventilation bag (8) with one hand then release the grip on the bag. Rapid bag re-expansion confirms efficient air intake.
- Block the patient valve/mask connector part and try to compress the bag. If the bag cannot be compressed with reasonable force, the valve is efficiently preventing backward escape of air.
- Place a reservoir bag, (6) or (7), or test lung (if available) over the patient valve. Compress the bag several times. This should fill the reservoir or test lung and confirm that the patient valve is able to efficiently direct air to the patient.
- Compress the filled reservoir bag. Air should vent to the atmosphere as indicated by lifting of the disk membrane at the base of the mask connector and not return to the ventilation bag (8).

4. **PRESSURE RELIEF REGULATOR**: The Infant and Child resuscitators feature a patient valve with a special pressure limiting device (2) mounted on the upper valve housing. If inspiration meets with pulmonary resistance of approximately 35±5 cmH_2O, the device opens, reducing the risk of stomach distension and / or barotrauma. A hissing sound can be heard when the device opens. If higher ventilation pressure is required, the pressure limiting device can be overridden with finger pressure on the plunger or disabled by depressing and turning the plunger.
5. If high concentrations of oxygen are needed, attach oxygen tubing (4) to the bag and an adjustable oxygen source, and attach an oxygen reservoir bag (6) or (7) to the bag.
6. Adjust oxygen flow to insure the oxygen reservoir bag remains fully or partially inflated during use.
7. When using a mask (3) attached to the resuscitator, be sure you have a tight seal and secure fit.
8. When using an endotracheal tube or tracheotomy tube, remove mask (3) and attach the resuscitation unit directly to the tube. The mask elbow provides a 15 mm I.D. port for this purpose.
9. **HAND STRAP**: Grab the bag with your hand. Adjust the hand strap (9) by loosening the loop from the hook then pull the strap to fit your hand, and finally reattach the loop to the hook.

Operation Instructions

If supplemental oxygen is needed, connect the oxygen source to the resuscitation bag oxygen connector.

1. Open patient's airway.
2. Clear patients mouth of foreign matter.
3. Apply mask firmly to the face. If the patient is intubated, attach the patient valve connector directly to the endotracheal tube. Squeeze and release the bag allowing enough time between inspirations for the patient to exhale and the bag to re-expand. Follow local protocol.
4. Observe the rise and fall of the patient's chest and listen for the air flow from the valve as the patient exhales.

IMPORTANT: If the patient's chest does not rise and fall with each breath or no airflow is present, the patient's airway or the patient valve itself may be blocked.

WARNING: TAKE IMMEDIATE ACTION by performing artificial respiration (mouth-to-mouth, mouth-to-barrier, mouth-to-tube resuscitation) or follow local protocol. The airway must be cleared before proceeding.

Performance and Specifications[1]

RESUSCITATOR MODEL	ADULT (>20KG)			CHILD (10-20KG)	INFANT (5-12kg)
MAXIMUM RATE	85 BPM			144 BPM	180 BPM
DELIVERED TIDAL VOLUM (ONE HAND RESUSCITATION)	830 ml			330ml	180 ml
PRESSURE RELIEF VALVE	Not provided			(Nominal) 35±5 cm H_2O	(Nominal) 35±5 cm H_2O
OXYGEN CONCENTRATION %					
FLOWRATE (LPM)	3	5	10	10	4
FREQUENCY (BPM)	12	12	12	20	30
TIDAL VOLUM (ml)	500	500	500	250	40
% O_2 W/ RESERVOIR	90%	98%	99%	100%	100%
% O_2 W/O RESERVOIR	34%	47%	66%	70%	85%
MAXIMUM MEASURED VOLUM					
BAG	1650ml			500 ml	230 ml
RESERVOIR	2900 ml			2900 ml	810 ml

Technical Specifications:

Operating Environmental Temperature Limits: -18°C to +50°C
Storage Environmental Temperature Limits: -40°C to +60°C
Expiratory Resistance: 1.8 cmH_2O @ 50 LPM
Inspiratory Resistance: 1.5 cmH_2O @ 50 LPM
Patient Valve Dead Space: 6.8 ml

Materials List:

Parts	**Material**
Face masks	Polyvinylchloride (PVC)
Flexible valve parts	Silicone Rubber (SI)
Compression bags	Polyvinylchloride (PVC)
Transparent valve parts	Polycarbonate (PC)
O_2 reservoir & O_2 tubing	Polyvinylchloride (PVC)
Hand strap hook and loop	Polypropylene

Disposal: Dispose of according to local protocols.

Symbols:

Unique product reference.

Manufacturing batch code.


Do not reuse.

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[1] Tested according to ISO 10651-4:2002 and ASTM-F920-93 product standards.