

The BAG™

Resuscitator - Newborn model

User Guide



Newborn
2.5-5 kg

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Improper assembly may affect performance.

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Date of issue: 2025-04
Laerdal Medical AS
P.O. Box 377, Tanke Sivilandsgate 30,
4002 Stavanger, Norway
www.laerdal.com

20-17980 Rev F

English (EN)

Note
This user guide applies to The BAG resuscitator – Newborn model. Information on the included face mask and the other accessories listed for The BAG, or other The BAG resuscitator sizes, are found in their separate user guides.

CLINICAL INDICATIONS

Device Description
Laerdal The BAG is a non-sterile single use self-inflating manual resuscitator. It may be used multiple times on a single patient when kept free from contamination.

Indication for Use
The BAG is indicated for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen.

Intended Use
The BAG provides positive pressure ventilation and allows spontaneous breathing with a face mask or an advanced airway.
The Newborn model is intended for patients 2.5 - 5 kg (5.5 - 11 lbs).

Intended Users
The BAG is intended to be used by healthcare professionals trained in resuscitation, delivering ventilatory support and in the use of manual resuscitators.

Clinical Benefits
The intended clinical benefit is positive impact on clinical outcome, by respiratory support that reduces probability of adverse outcomes, such as morbidity and mortality caused by hypoxia.

Clinical Outcome
Desired outcome of ventilation is oxygenation of the patient, often evaluated using SpO₂, EtCO₂, blood gas analysis or other methods of analysis.

Known Side Effects
Gastric Insufflation
Oxygen Toxicity

Contraindications
None known.

IMPORTANT INFORMATION

Read this User Guide and become familiar with the operation of The BAG resuscitator prior to use. Use the resuscitator only as described in this User Guide.

Warnings
A Warning states a condition, hazard, or unsafe practice that can result in serious personal injury or death.

- Storage of The BAG's Ventilation Bag in a deformed state can cause permanent deformations and risk of inadequate ventilation of the patient. Ensure that The BAG is protected from mechanical impact or deformation. Remove deformed resuscitators from storage and replace with new ones. If ventilation is necessary and no replacement is available, perform ventilation with The BAG as best possible.
- The BAG is for single patient use only. It is not designed for reprocessing. Reuse with multiple patients will lead to risk of cross contamination. Laerdal is not responsible for any consequence of reprocessing or multiple patient reuse.
- Use of The BAG for single patient multiple uses for prolonged time periods increases risk of infection of the patient or resuscitator malfunction.

Cautions
A Caution states a condition, hazard, or unsafe practice that can result in minor personal injury or damage to the product.

- The BAG should only be used by persons who have received adequate training in the use of resuscitators.
- The BAG is intended for a maximum of 24 hours of accumulated use per patient.

Notes
Important information about the product or its operation.

- Should any serious malfunction, undesirable incident with, or deterioration in the functionality or performance of the device occur, contact Laerdal promptly. The competent authority where the incident took place and/or the device was used should also be notified.

INSTRUCTIONS FOR USE

- A** Device Overview
- Patient Port Connector (OD 22 mm/ID 15 mm)
 - Expiratory Port / PEEP Connector (OD 30 mm)
 - Manometer Port with Cap (See Figure D)
 - Pressure Relief Valve
 - Ventilation Bag
 - Oxygen Tube (not detachable)
 - Protective Ribbon
 - Oxygen Reservoir Bag

Note
The BAG does not have a medicinal part.

B Function Test

Warnings

- Perform the Function Test before every clinical use.
- If the device fails the Function Test, remove it from service and do not use.

Before performing the Function Test, ensure that the Manometer Cap is closed (see Figure D).

- Check the device: Inspect for being clean and dry, and without deformation or damage.
- Squeeze the Ventilation Bag and check that the lip valve opens. Check that the lip valve is closing after each ventilation.
- Test opening of the Pressure Relief Valve: Ensure that the Pressure Relief Valve is not locked (see Figure E). Block the Patient Port Connector. Squeeze the Ventilation Bag firmly and check that air is released from the Pressure Relief Valve.
- Test for no leakage: Block the Patient Port Connector and prevent the Pressure Relief Valve from lifting/releasing air. Squeeze the Ventilation Bag firmly and check that the Ventilation Bag does not deflate.
- Optional: Connect to an oxygen source (see Figure C 5.1) with a flowmeter and test filling of Oxygen Reservoir Bag. Check that the Oxygen Reservoir Bag inflates (see Figure C 5.2).

Note
The BAG with attached accessories can be returned into its polybag for further storage. The polybag's zip-lock seal can be closed to reduce exposure to contamination.

C Assembling Accessories

- Attach the mask (1a) or connect to a breathing tube (not provided by Laerdal) (1b).
- Optional: Attach The BAG PEEP Valve.
- Optional: Attach The BAG Manometer.

D Closing of Manometer Cap

Ensure that the Manometer Cap is always closed, unless a Manometer is attached.

Warning
If the Manometer Port is left open during ventilations, there will be forward leakage and risk of hypoventilation.

E Pressure Relief Valve

The Pressure Relief Valve lifts slightly to release air when airway pressure exceeds approximately 40 cmH₂O (see Fig. C 3).

To provide higher airway pressure:

- Use a finger to prevent the Pressure Relief Valve from lifting.
- Squeeze the Ventilation Bag firmly to increase airway pressure.

Warning
To avoid the risk of barotrauma, do not override the Pressure Relief Valve unless it is clinically justified. Ensure that the Pressure Relief Valve is unlocked immediately after the clinical need is resolved.

F Rotating the Patient Port Connector and Use of the Hand Strap

The Patient Port Connector can be rotated to allow for repositioning of the Ventilation Bag without disconnecting the mask or breathing tube.

G Removal of Oxygen Reservoir Bag

To provide reduced oxygen concentrations to the patient, (see Oxygen Tables), the Oxygen Reservoir Bag can be detached from The BAG resuscitator:

- Grab the Oxygen Reservoir Bag's connector. Apply force to detach it from The BAG.

Caution
Pulling by bag's foil material may damage the reservoir bag.

The Oxygen Reservoir Bag can be reattached if needed.

Operating The BAG

With a face mask

- Remove The BAG Mask's protective sleeve. Ensure that the face mask is suitable for use on the patient
- See The BAG Mask's User Guide for guidance on use of mask.

With an advanced airway (e.g., ET-tube or laryngeal tube)

- Remove the Oxygen Tube's Protective Ribbon. Connect the Oxygen Tube to a suitable external oxygen source. Set oxygen flow as required for the patient.
- Connect The BAG's Patient Port Connector to the patient's advanced airway.

Positive pressure ventilation

- Squeeze the Ventilation Bag in accordance with clinical protocol. If needed, use the Hand Strap for support.
- Observe the patient's chest rise during ventilation.
- Allow patient to exhale.
- Stop ventilation as required by clinical protocol.

Ventilatory support of spontaneously breathing patient

- Hold the Ventilation Bag. If needed, use the Hand Strap for support.
- Allow the patient to inspire oxygen from the face mask or advanced airway.
- Observe the patient's chest rise and oxygenation.
- Allow patient to exhale.
- If larger tidal volume is required, support the patient's inspiratory efforts by synchronized squeezing of the Ventilation Bag.
- Stop ventilation as required by clinical protocol.

Warnings

- Incorrect operation of the resuscitator can be hazardous.
- Do not block the inlet or exhaust ports of The BAG or its accessories.
- Use the correct The BAG size model resuscitator for the ideal body mass of the patient to avoid the risk of hypoventilation or barotrauma.
- To avoid the risk of barotrauma, do not use abrupt and forceful compressions unless it is clinically justified because they can cause high airway pressures.
- Use of The BAG PEEP Valve is recommended in the case that Positive End-Expiratory Pressure (PEEP) is indicated for the patient.
- Care should be taken when using The BAG on patients with severe pulmonary disease. Applied

ventilation pressure should be adjusted and monitored according to the patient's condition.

- Care should be taken when using The BAG on patients with severely congested airways. Consider removing congestion from the oropharyngeal airway. Use of The BAG on patients with severely congested airways may result in a reduction in expected oxygenation.
- No pressurized gases or medications should be applied between the BAG patient valve and an artificial airway. This can lead to patient harm.
- The BAG and masks are not intended for use in delivery of medications, such as anesthetic gases.

Use with Oxygen gas

Use with high oxygen concentration
Set oxygen flow to 5 l/min. Readjust oxygen flow in accordance with the Oxygen Concentration Tables.

Spontaneous breathing with high oxygen concentration
Set oxygen flow to 5 l/min.
The highest oxygen concentration can be achieved when used with The BAG PEEP Valve, e.g., set at the lowest PEEP setting.

Low oxygen concentration use – Pre-blended by an oxygen mixer
For a more accurate lower delivered oxygen concentration, use an oxygen blender/mixer set to the desired oxygen concentration. Set a flow of 15 l/min of the blended gas to minimize dilution with ambient air by the resuscitator during ventilation.

Low oxygen concentration use – Without Oxygen Reservoir Bag
Removing the Oxygen Reservoir Bag allows more dilution of the oxygen gas with ambient air. See Figure G.

Warnings

- Avoid using an oxygen concentration more than that which is clinically required by the patient. Delivering excessive oxygen can increase the risk of oxygen toxicity, e.g., pulmonary damage.
- Open flames during resuscitation with oxygen are dangerous and are likely to result in fire or death. Do not allow open flames or sparks within 2 meters of the resuscitator or any oxygen-carrying accessories.
- Do not lubricate fittings, connections, tubing, or other accessories of the resuscitator to avoid the risk of fire and burns.

Cautions

- When using supplemental oxygen, the flow from its source should be monitored. Delivery of supplemental oxygen greater than 30 l/min may result in inadvertent PEEP or device malfunction.
- If the Oxygen Reservoir Bag stops refilling during use, it may be an indication of disconnected or blocked Oxygen Tube, or torn Oxygen Reservoir Bag or empty oxygen supply.

Contamination
If the Patient Valve becomes contaminated with vomit or fluids during ventilation, first consider using another suitable resuscitator and mask if they are available with minimum delay.

To clear the Patient Valve from contaminants:

- Disconnect The BAG from the face mask or advanced airway.
- Tap the Patient Valve with the Patient Port Connector against your gloved hand to shake free any contaminant and squeeze the Ventilation Bag to deliver several sharp breaths to expel the contaminant from the Patient Valve.

When the contaminant has been cleared:

- Perform the Function Test as described in Figures C2 and C3. Repeat Step 2 above if necessary.
- Proceed with therapy.

Warnings

- Patient expired gas is potentially infectious. Breathing filters can reduce but not eliminate contamination risk.
- Use in contaminated environments can be hazardous as the patient may inhale gas from the atmosphere.

Accessories
List of accessories/devices intended for The BAG Newborn version resuscitator:

- The BAG Mask: Size 1.
- The BAG Manometer
- The BAG PEEP Valve 2-10 cmH₂O
- The BAG PEEP Valve 5-20 cmH₂O
- The BAG Bag Refill Valve Adapter – for connection of a bag refill valve (not provided by Laerdal) for supplying oxygen.

Caution
The use of third-party devices and oxygen delivery devices with The BAG may affect safety and/or performance. Consult with the manufacturer of the third-party device to verify compatibility with The BAG and obtain information on possible performance changes.

SPECIFICATIONS

Standards
The BAG resuscitator complies with the following standards:

- ISO 10651-4:2002 - Lung ventilators Part 4: Particular requirements for operator-powered resuscitators
- ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- EN 1789:2020 – Medical vehicles and their equipment
- ASTM F2052-15: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Symbol Glossary		
	This medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 for medical devices.	
	Caution: Federal law restricts this device to sale by or on the order of a physician.	
	Medical Device	
	Unique Device Identifier	
	Not made with natural rubber latex	
	MR Conditional	
	Do not re-use	
	Single patient multiple use	
	Consult Operators Manual	

Global 1-Year Limited warranty: www.laerdal.com

