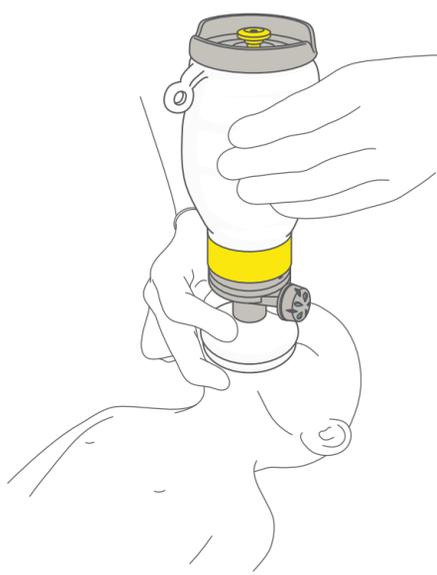


User Guide

Upright with PEEP

Newborn Bag-Mask

REUSABLE - AUTOCLAVABLE



REF Cat. no. 846060



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SPECIFICATIONS

Temperature and Environment	
Operating temperature	- 18 °C to 50 °C
Storage temperature	- 40 °C to 60 °C
Performance Specifications	
Dead space	Approx. 5 mL (water volume)
Tidal volume	>150 mL
Total bag volume	Approx. 320 mL
Expiratory resistance	with PEEP: <15 cmH ₂ O at 5 L/min
	without PEEP: <2.5 cmH ₂ O at 5 L/min
Inspiratory resistance	with PEEP: <1 cmH ₂ O at 5 L/min
	without PEEP: <1 cmH ₂ O at 5 L/min
PEEP value/Pressure range	6 ± 2 cmH ₂ O
Lifetime parameters	
Shelf-life	5 years
Expected Service Life	100 cycles of reprocessing
Measurements	
Patient Connector (conical)	15 mm inner diameter; 22 mm outer diameter
External dimensions (with newborn Mask size 1)	Approximately 74 x 87 x 217 mm
Mass (with newborn Mask size 1)	Approximately 200 grams
Materials	
Hard plastic components	Polysulfone (PSU)
Soft plastic components	Silicone rubber
Spring	Stainless steel

REGULATORY

Meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators – Particular requirements for operator-powered resuscitators.

Symbol Glossary	
	Medical Device
	This medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 for medical devices.
	Not made with natural rubber latex

CLINICAL INDICATIONS

Device Description

Upright with PEEP is a self-inflating manual resuscitator that is intended for patients requiring total or intermittent ventilatory support.

Indication for Use

Upright with PEEP is intended for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen.

Intended Use

Upright with PEEP provides positive pressure ventilation and allows spontaneous breathing with a face mask or an artificial airway.

Intended for patients up to 10 kg (22 lbs).

Intended Users

Upright with PEEP is intended to be used by healthcare professionals trained in delivering ventilatory support and in the use of manual resuscitators.

Clinical Benefits

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 method of analysis.

Known Side Effects

Gastric Insufflation
Oxygen Toxicity

Contraindications

No known contraindications for use.

IMPORTANT INFORMATION

Read this User Guide and become familiar with the operation and maintenance of the device prior to use. Use the product only as described in this User Guide.



Warnings and Cautions

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

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



Notes

A note states important information about the device or its operation.



Warnings

- Upright with PEEP should only be used by persons who received sufficient training in its use. Incorrect operation of the resuscitator can be hazardous.
- Resuscitators should not be used with supplemental oxygen where smoking is permitted or when fire, flame, oil or grease is in close proximity.
- This resuscitator should not be used in toxic or hazardous atmosphere.
- Do not use Upright with PEEP if you have any reason to be concerned about its functionality.
- For proper function, ensure that Upright with PEEP components are not mixed and confused with similar-looking non-Laerdal components. All Upright with PEEP components are marked LAERDAL, as shown on page 2.
- Care should be taken when using the Upright with PEEP on patients with severe pulmonary disease or severely immature lungs. Applied pressure should be adjusted and monitored according to the patient's condition. Note that a manometer is not supplied by Laerdal for use with the Upright with PEEP but a manometer is possible to connect to the patient port with an appropriate adapter compatible with an ISO 5356-1 connector.
- Care should be taken when using Upright with PEEP on patients with severe facial anomalies or when applying other medical devices which may conflict with the mask as mask leakage may occur. If mask face sealing is not possible to achieve consider using alternative airway device.
- Care should be taken when applying pressure to the mask to avoid facial damage, especially in the case of pediatric patients, infants, pre-terms, patients..
- Use of the Newborn Masks provided on patients over 5 kg may result in poor fit. Larger masks should be used on patients over 5 kg. Note that these masks are not provided with Upright with PEEP.
- Care should be taken when using Upright with PEEP on patients with severely congested airways. Consider removing congestion from the oral cavity. Use of Upright with PEEP on patients with severely congested airways may result in a reduction in expected oxygenation.

- No pressurized gases or medications should be applied between the Upright with PEEP patient valve and an artificial airway. This can lead to patient harm.
- Upright with PEEP is not intended for use in delivery of medications, such as anesthetic gases.
- Do not pull open slit on PEEP membrane.
- Do not attempt to block the PEEP cap or port, which could prevent patient expiration.
- High ventilation rates (> 30 breaths per minute) with high-compliance lungs, may restrict patient expirations and increase PEEP above 8 cmH₂O.
- Use of Newborn PEEP on infants larger than 5 kg may result in higher PEEP.
- At freezing temperatures, PEEP function could be reduced or lost. Absence of a hissing sound after each ventilation may indicate this.
- Not to be used in a respiratory circuit or for providing CPAP.
- Not suitable for providing free-flow of oxygen to patient.
- Check PEEP levels regularly with a manometer.
- No pressurized gases or medications should be applied between the Upright with PEEP patient valve and an artificial airway.

Cautions

- Not tested to ambulance standards.
- The hard plastic components of the resuscitator are incompatible with polar solvents such as ethanol and isopropyl alcohol.
- An oxygen blender is recommended if more precise oxygen concentrations are required, for example for pre-terms.
- The use of the PEEP membrane is recommended in the case that PEEP is indicated for the patient.
- Improper assembly of Upright with PEEP after reprocessing may affect performance.
- 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.

Notes

- The upright patient port does not have a swivel function, care should be taken when using together with an artificial airway.
- 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.

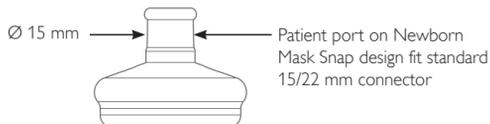
Warranty

Refer to one-year Laerdal Global Warranty for terms and conditions. For more information, visit www.laerdal.com.

USING UPRIGHT WITH PEEP

Orientation: Upright with PEEP is operated as a normal resuscitator, with the bag having a vertical stance over the mask.

Newborn Mask - Snap Design: The mask fits with standard 15 mm inner-diameter conical connectors, as defined by ISO 5356-1. Check fit before use with other devices. When used with Upright with PEEP, the mask attaches with a snap fit when pressed completely into place.



- Upright with PEEP can provide supplemental oxygen only when used with the Oxygen kit (sold separately). Details of use are provided in the Oxygen kit's User Guide.
- Upright with PEEP may be reused provided reprocessing procedures (page 2) are followed between each patient use. It must be cleaned and disinfected before first use.
- Pressure Release Valve: Upright with PEEP has a pressure release valve ("pop-off") which releases air when pressure to the patient exceeds 30-45 cm H₂O. A hissing sound can be heard when the valve opens. If higher airway pressure is needed, press downwards on the valve with the index finger while squeezing the bag.

CLINICAL USE

Caution

The resuscitator components must be cleaned and disinfected before first patient use.

Operating Upright with PEEP with face mask:

- Connect a suitable face mask
- Connect to external O₂ source, if applicable.
- Place mask over face and check for seal.
- Squeeze the Ventilation Bag in accordance to clinical protocol.
- Observe patient chest rise during ventilation.
- Allow patient to exhale.
- Stop ventilation as required by clinical protocol.

Operating the Upright with PEEP with advanced airway:

Before attaching the Upright with PEEP please ensure that the artificial airway is securely in place, and secured as the Upright with PEEP may shift the tube.

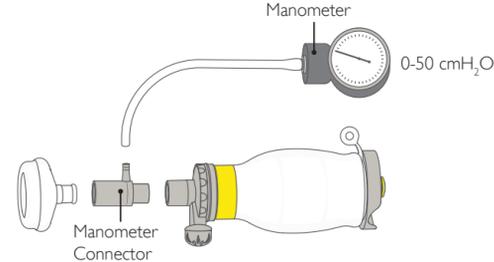
- Connect to external O₂ source, if applicable.
- Connect to advanced airway of intubated patients.
- Squeeze the Ventilation Bag in accordance to clinical protocol.
- Observe patient chest rise during ventilation.
- Allow patient to exhale.
- Stop ventilation as required by clinical protocol.



Notes

The oxygen source should be able to be adjusted to provide a flow relevant to the Upright with PEEP. See tables in Upright Oxygen kit's user guide regarding achievable oxygen concentration at varying flows for more information.

Manometer Use



Peak Inspiratory Pressure (PIP) and PEEP can be monitored when a manometer is connected between Upright with PEEP's Patient Port Connector and the face mask. Check PEEP pressure regularly with a manometer connected with a manometer connector between Upright with PEEP and the mask or airway adjunct.

Positive End-Expiratory Pressure (PEEP) Valve

The included Newborn PEEP valve membrane can be attached to Upright with PEEP's expiration port. See section Disassembly and Reassembly illustration to locate the expiration port.

The PEEP membrane opens with a popping sound during each patient expiration. Other types of PEEP valves cannot be fitted to Upright with PEEP.

PEEP can be deactivated by removing the PEEP valve membrane. Check PEEP pressure regularly with a manometer.

Contamination: If the Patient Valve becomes contaminated with vomitus or mucus, disconnect Upright with PEEP from the patient and clear the valve as follows:

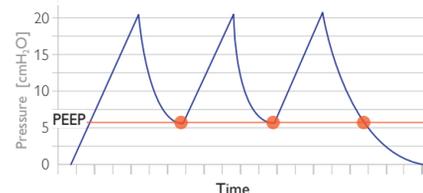
- Tap the Patient Valve with the patient port against your gloved hand

- to shake free any contaminant and squeeze the silicone bag to deliver several sharp breaths through the Patient Valve to expel the contaminant.
- If contaminant does not clear, disassemble the Patient Valve and rinse. Reassemble the device and test in accordance with page 2.

If any components are loose, tighten or reassemble the device in accordance with page 2.

Expected PEEP Performance

PEEP shall be measured as the end expiratory pressure between inflations (usually the lowest pressure delivered between inflations).

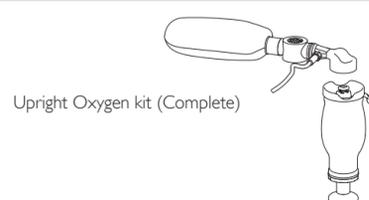


PEEP value between continuous ventilations is typically 6 cmH₂O with a tolerance range of 4-8 cmH₂O, as illustrated in the graphs below. For high ventilation rates with a high compliance lung, expected PEEP value increases.

ACCESSORIES AND SPARE PARTS

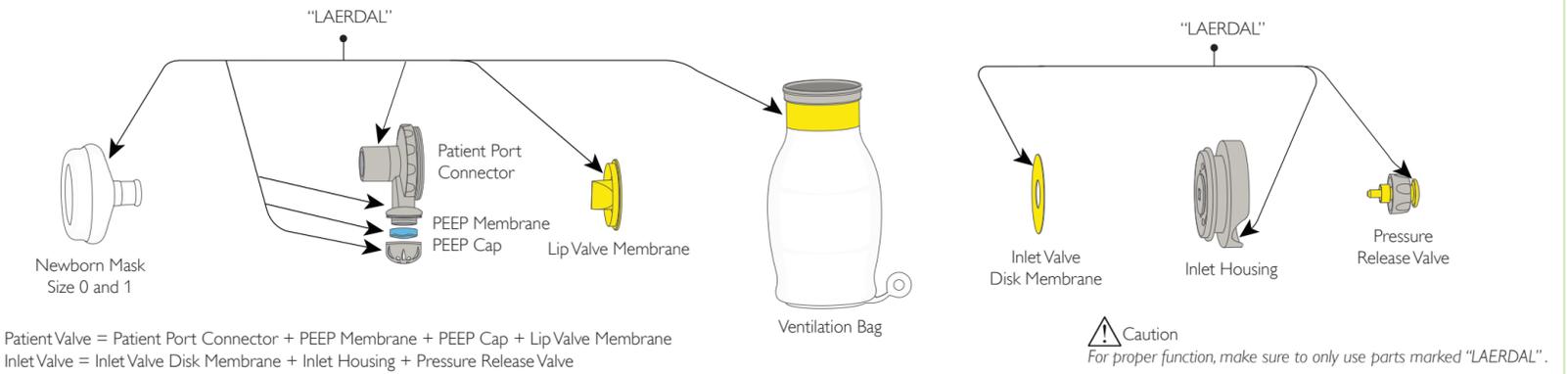
Cat. no	Description
846156	Newborn Mask - Snap design – Size 0*
846157	Newborn Mask - Snap design – Size 1*
846165	Newborn PEEP membrane and cap – 1 set
846151	Upright Oxygen kit Complete
846130	Oxygen reservoir bag and tubing
856155	Upright valves and membranes kit* (lip valve, inlet valve disc membrane)

* Masks are bulk packed: 10 masks in 1 polybag.



Overview

Items Included



Reprocessing Instructions

Disassembly

To disassemble follow steps 1-6.



Cleaning and Sterilization/ Disinfection

Cleaning

1. Disassemble	2. Manual Cleaning	3. Rinsing	4. Post-Treatment
Always disassemble before cleaning. 	Prepare a solution of clean lukewarm water and mild dishwashing soap in a clean tray. Fully immerse all parts in the cleaning solution. Using soft bristled brush, clean the parts for a minimum 2 minutes.	Rinse parts under running lukewarm water for a minimum of 1 minute to remove all soil and soap. Repeat previous cleaning steps as needed until all parts are visibly clean.	Before sterilization/ disinfection dry with a clean gauze/cloth.

Sterilization/ Disinfection

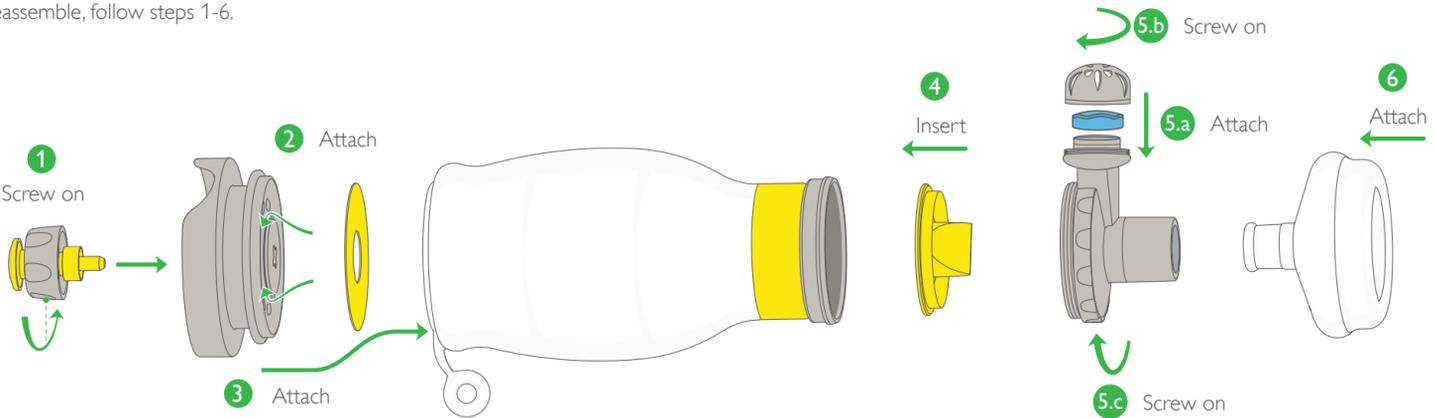
1. Choose one of the following methods:	2. Post-Treatment
Autoclaving Sterilize by gravity displacement steam autoclaving at 136 °C and 2.0 kg/cm ² for 10-20 min. 	Allow parts to air dry in protected space.
Boil* Boil all parts in clean water for 10 min. *Validated at approximately sea-level pressure. 	

Post-Sterilization/ Disinfection

1. Inspect	2. Reassemble	3. Function Test
Visually inspect each part for damage and cleanliness /mineral deposits. If not clean repeat cleaning and sterilization process. Caution Removed damaged, crazed, cracked or worn parts from use.	Reassemble as shown in Assembly. Note Improper assembly of the Upright with PEEP after reprocessing may affect performance.	Test using steps as shown in Function Test Before Use section.

Assembly

To reassemble, follow steps 1-6.



Assembly Highlights

3 Ventilation Bag and Inlet Valve Ensure that the ventilation bag's lip is not twisted or tucked under in the reassembly procedure.	Patient Port Connector Attach PEEP membrane (5.a) onto the patient port connector before attaching the PEEP cap (5.b) during assembly.
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Function Test Before Use

1. Lip Valve Membrane Function	2. Pressure Release Valve & Inlet Valve Function	3. Product Sealing	4. PEEP Membrane Function
 Squeeze the bag. Check that the yellow valve opens and closes with every squeeze.	 Seal the mask with a hand. Squeeze the bag forcefully. Check that air is released from the pressure release valve. Keep the mask sealed against hand. Release the squeezed bag. Check that the bag re-expands without resistance.	 Keep the mask sealed against the hand. Press the pressure release valve down. Squeeze the bag and check that there is no leakage.	 Check that PEEP membrane slit opens and seals fully. Hold Upright firmly at the neck. Press other hand upwards against the mask's sealing cuff so that air inside the mask is pushed into Upright and out the expiration port with the PEEP Valve membrane. Repeat 3 times.

Cautions

- If any of the above tests fail, disassemble Upright with PEEP, inspect the components, reassemble and repeat the complete procedure in "Function Test Before Use" section. Remove any damaged parts if necessary and retest.
- The resuscitator is not provided sterile. The resuscitator and mask must be cleaned and disinfected/sterilized prior to initial use.
- It is recommended that the highest level of disinfection/sterilization possible is used for patients that may have compromised immune defense, such as pre-term baby or in the case of outbreaks of highly transmissible pathogens.
- If Upright with PEEP is stored as back-up in an area with potentially high levels of airborne pathogens it should be considered to store the Upright in an air-tight container to avoid contamination.
- The use of cleaning and disinfection procedures not described in this section may have adverse effects on the Upright with PEEP material and/or performance and may not be effective for disinfecting the Upright with PEEP.