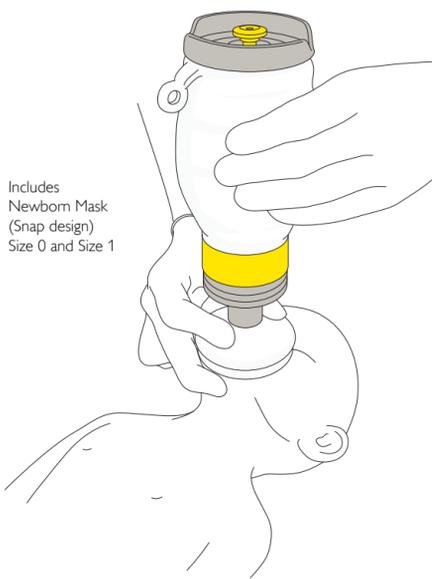


User Guide

Upright Resuscitator

Newborn Bag-Mask

REUSABLE - AUTOCLAVABLE



Includes
Newborn Mask
(Snap design)
Size 0 and Size 1

REF Cat. no. 8560533



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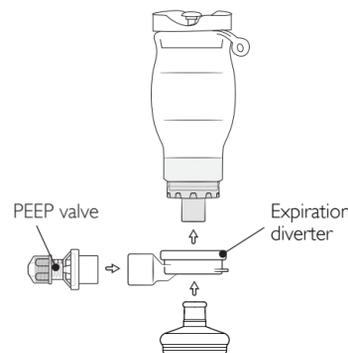
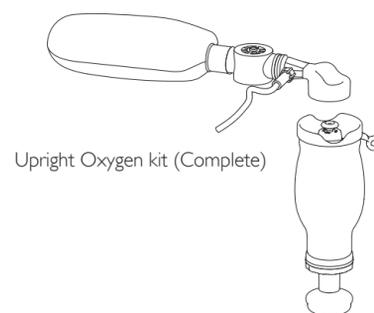


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ACCESSORIES AND SPARE PARTS

Cat. no	Description
856156	Newborn Mask - Snap design – Size 0*
856157	Newborn Mask - Snap design – Size 1* * 10 pcs
8561733	Oxygen kit (Complete) includes Oxygen Adaptor, Valve, Reservoir Bag and Tubing
846130	Oxygen Reservoir Bag and Tubing
856155	Upright Valves and Membranes kit* (Lip Valve, Inlet Valve Disc Membrane) * 10 pcs
850500	Expiration diverter (OD 30 mm)



CLINICAL INDICATIONS

Device Description

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

Indication for Use

The Upright Resuscitator ('Upright') is intended for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen.

Intended Use

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

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

Intended Users

The Upright 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.

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 should only be used by persons who have received sufficient training in its use. Incorrect operation of the Upright can be hazardous.
- Do not use the Upright if you have any reason to be concerned about its functionality.
- Resuscitators should not be used with supplemental oxygen where smoking is permitted or when fire, flame, oil or grease is in close proximity.
- For proper function, ensure that Upright components are not mixed and confused with similar-looking non-Laerdal components. All Upright components are marked LAERDAL, as shown on page 2.
- Care should be taken when using the Upright 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, but a manometer is possible to connect to the patient port with an appropriate adapter compatible with a ISO 5356-1 connector.
- Care should be taken when using the Upright 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 especially in the case of pediatric, infant and preterm 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.

- Care should be taken when using the Upright on patients with severely congested airways. Consider removing congestion from the oral cavity. Use of the Upright 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 patient valve and an artificial airway.
- The Upright is not intended for use in delivery of medications, such as anaesthetic gases.

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 a PEEP valve (not provided by Laerdal) is recommended in the case that PEEP is indicated for the patient. Note that it is necessary to use the Expiration diverter to attach a PEEP valve.
- Improper assembly of Upright after reprocessing may affect performance.
- The use of third-party devices and oxygen delivery devices with Upright may affect safety and/or performance. Consult with the manufacturer of the third-party device to verify compatibility with Upright and obtain information on possible performance changes.

Notes

- 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.
- The Upright patient port does not have a swivel function. Care should be taken when using with an artificial airway.

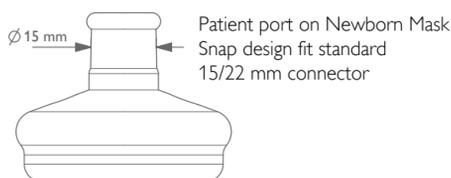
Warranty

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

USING UPRIGHT

Orientation: Upright 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, the mask attaches with a snap fit when pressed completely into place.



Upright can provide supplemental oxygen only when used with the accessory Oxygen Kit (sold separately). Details of use are provided in the Oxygen kit's User Guide.

Upright 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 has a pressure release valve ("pop-off") which limits the airway pressure to 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 the Upright with face mask:

1. Connect a suitable face mask.
2. Connect to external O₂ source, if applicable.
3. Place mask over face and check for seal.
4. Squeeze the Ventilation Bag in accordance to clinical protocol.

5. Observe patient chest rise during ventilation.
6. Allow patient to exhale.
7. Stop ventilation as required by clinical protocol.

Operating the Upright with advanced airway:

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

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

The resuscitator may be fitted with the Laerdal LSR Expiration Diverter. Attach firmly to the Patient Port. Attach a suited PEEP valve if PEEP is indicated for the patient. Check PEEP levels regularly with a manometer.

Note

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

Contamination: If the Patient Valve becomes contaminated with vomit during ventilation, disconnect the resuscitator from the patient and clear the Patient 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 and test in accordance with page 2.

SPECIFICATIONS

Operating temperature	-18 °C to 50 °C	
Storage temperature	-40 °C to 60 °C	
Expiratory resistance	<2.5 cm H ₂ O at 5 LPM	
Inspiratory resistance	<0.5 cm H ₂ O at 5 LPM	
Tidal volume	>150 ml	
Dead space	4 ml (water volume)	
External dimensions (with Newborn Mask size 1)	Approximately 72 mm x 85 mm x 217 mm	
Mass (with Newborn Mask size 1)	Approximately 190 grams	
Materials	Hard plastic components	Polysulfone (PSU)
	Soft plastic components	Silicone rubber
	Spring	Stainless steel
Lifetime parameters	Shelf-life	5 years
	Expected Service Life	100 cycles of reprocessing

REGULATORY

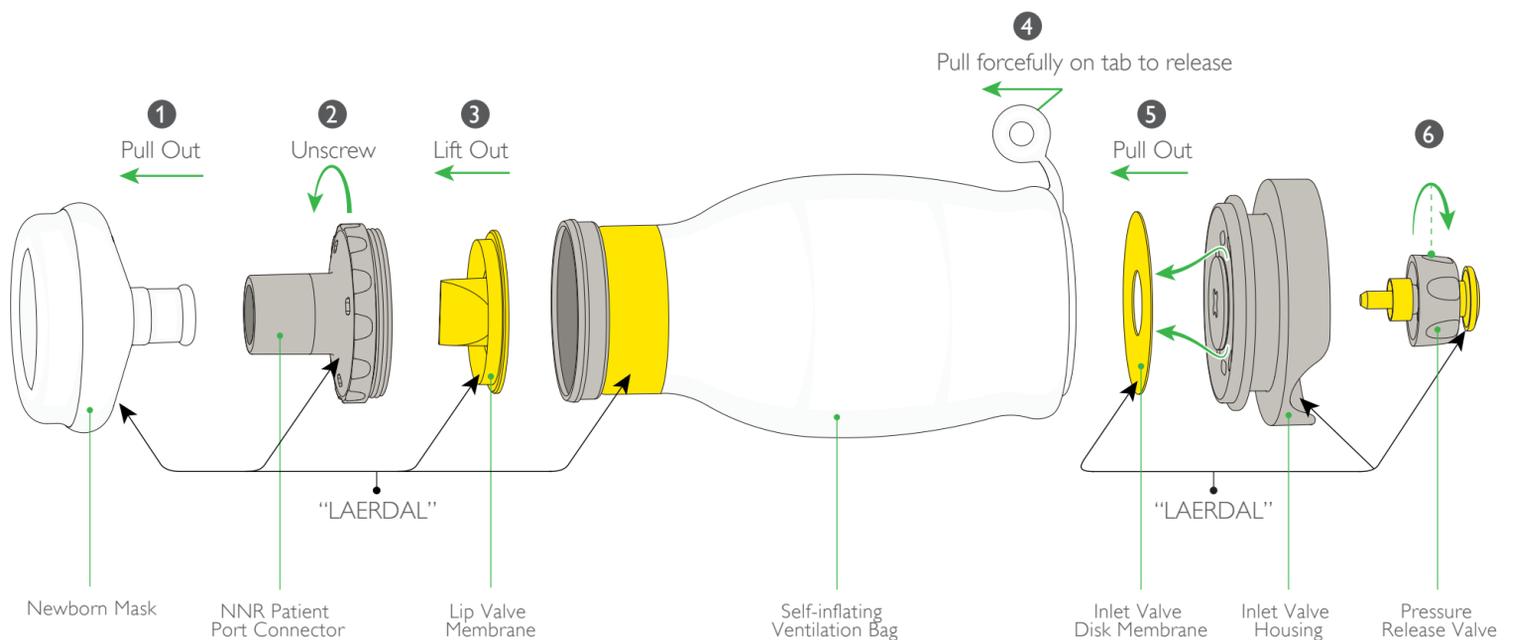
Meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators – Particular requirements for operator-powered resuscitators.

MD	Medical Device
CE 2460	This medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 for medical devices.
LATEX	Not made with natural rubber latex.

Reprocessing instructions

1. Product overview

To dismantle, follow steps 1-6. To reassemble, follow the steps in reverse.



⚠ Cautions

- Do not disassemble parts beyond the steps shown.
- For proper function, make sure to only use parts marked LAERDAL (locations as shown above).

2. Cleaning and Disinfection procedure

1. Dismantle	2. Clean	3. Disinfect by one of the methods	4. Dry and Inspect	5. Assemble and Test
<p>Always disassemble before cleaning.</p>	<ol style="list-style-type: none"> 1. Prepare a solution of clean lukewarm water and mild dish washing soap in a clean tray. 2. Fully immerse all parts in the cleaning solution. 3. Using soft bristled brush, clean the parts for a minimum 2 minutes. 4. Rinse parts under running, lukewarm water for a minimum of 1 minute to remove all soil and soap. 5. Repeat above steps until all parts are visibly clean. 	<p>100 °C 10 minutes</p> <p>Boiling*</p> <p>Boil all parts in clean water for 10 min.</p> <p><small>*Validated at approximately sea-level pressure</small></p> <p>OR</p> <p>Steam 136 °C 10-20 minutes</p> <p>Autoclaving</p> <p>Sterilize by gravity displacement steam autoclaving at 136 °C and 2.0 kg/cm² for 10-20 min.</p>	<ol style="list-style-type: none"> 1. Allow parts to air dry in a protected space. 2. Visually inspect each part for damage and cleanliness / mineral deposits. <p>⚠ Caution Remove damaged or unclean parts from service.</p>	<p>Reassemble Upright.</p> <p>Test usings steps shown below.</p> <p>Note Improper assembly of the Upright after reprocessing may affect performance.</p>

⚠ Cautions

- The resuscitator is not provided sterile. The resuscitator and mask must be cleaned and disinfected 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 a pre-term baby or in the case of outbreaks of highly transmissible pathogens.
- The use of cleaning and disinfection procedures not described in this section may have adverse effects on the Upright material and/or performance and may not be effective for disinfecting the Upright.
- If Upright 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.

3. Testing before use

1. Lip valve function	2. Pressure release valve	3. Inlet valve opening	4. Product sealing
<p>Squeeze the bag. Check that the yellow valve opens and closes with every squeeze.</p>	<p>Seal the mask against your hand. Squeeze the bag forcefully. Check that air is released from the pressure release valve.</p>	<p>Keep the mask sealed against your hand. Release the squeezed bag. Check that the bag re-expands without resistance.</p>	<p>Check that the silicone bag's lip is not twisted or tucked under.</p> <p>Keep the mask sealed against your hand. Press the pressure release valve down. Squeeze the bag and check that there is no leakage.</p>

⚠ Cautions

- If any of the above tests fail: Dismantle Upright, inspect that components, reassemble Upright and repeat the complete "Testing before use" procedure (Section 3).
- If Upright fails function tests it is to be removed from service and not used. Inspect all parts for damage. Replace any damaged parts if necessary and retest.