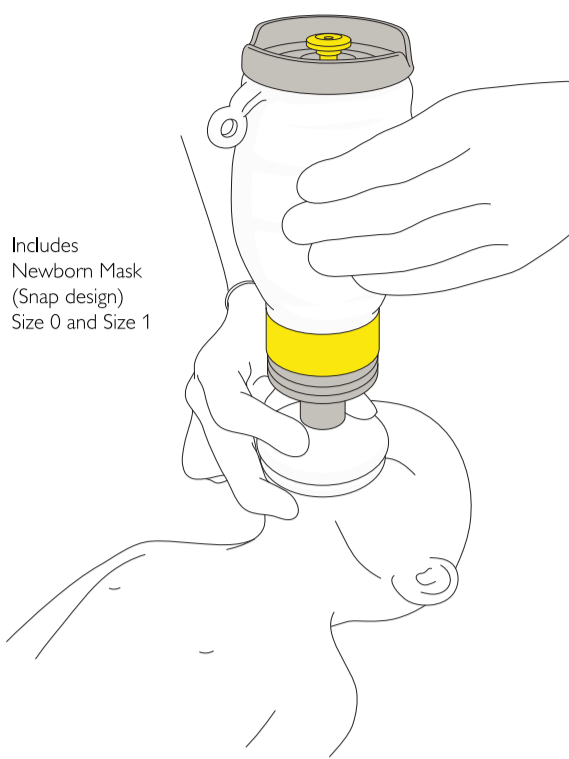


# User Guide

## Laerdal

### Upright Resuscitator

REUSABLE - AUTOCLAVABLE



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

REF Cat. no. 846050



© 2022 Laerdal Medical AS, All rights reserved.

US and international design registration.  
Laerdal® is a trademark or registered trademark  
of Laerdal Medical AS.

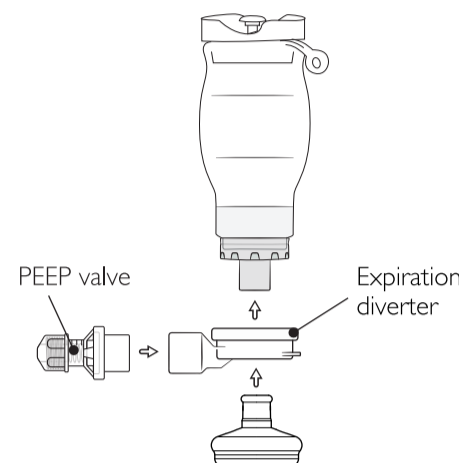
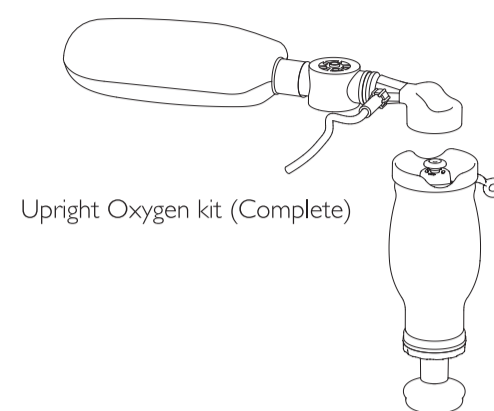


Manufactured in China for:  
Laerdal Medical AS, Tanke Svilandsgate 30  
P.O. Box 377, 4002 Stavanger, Norway  
Tel : +47 51 51 17 00

[www.laerdalglobalhealth.com](http://www.laerdalglobalhealth.com)

#### 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
846131	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)



20-20084 Rev A

#### 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 a self-inflating manual resuscitator that 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 SpO<sub>2</sub>, EtCO<sub>2</sub>, 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.
- 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 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.
- 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 oropharyngeal airway. Use of the Upright on patients with severely congested airways may result in a reduction in expected oxygenation.

- The Upright is not intended for use in delivery of medications, such as anaesthetic gases.

- The Upright is not intended for use with advanced airways.

##### ⚠ Cautions

- The resuscitator is not intended for use in an ambulance.

- The hard plastic components of the resuscitator and the mask cover 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.

##### 🗨 Note

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.

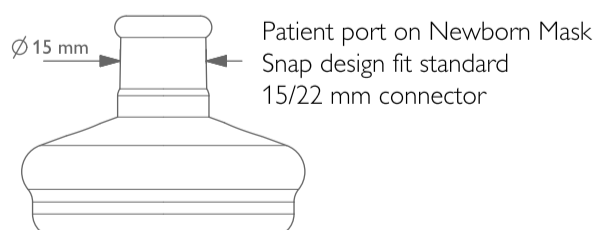
##### Warranty

Refer to one-year Laerdal Global Warranty for terms and conditions. For more information, visit [www.laerdal.com](http://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.

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 H<sub>2</sub>O. 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

Operating the Upright with face mask:

1. Connect a suitable face mask.
2. Connect to external O<sub>2</sub> 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.

##### ⚠ Warning

Incorrect operation of the resuscitator can be hazardous.

##### 🗨 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 <sub>2</sub> O at 5 LPM	
Inspiratory resistance	<0.5 cm H <sub>2</sub> 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

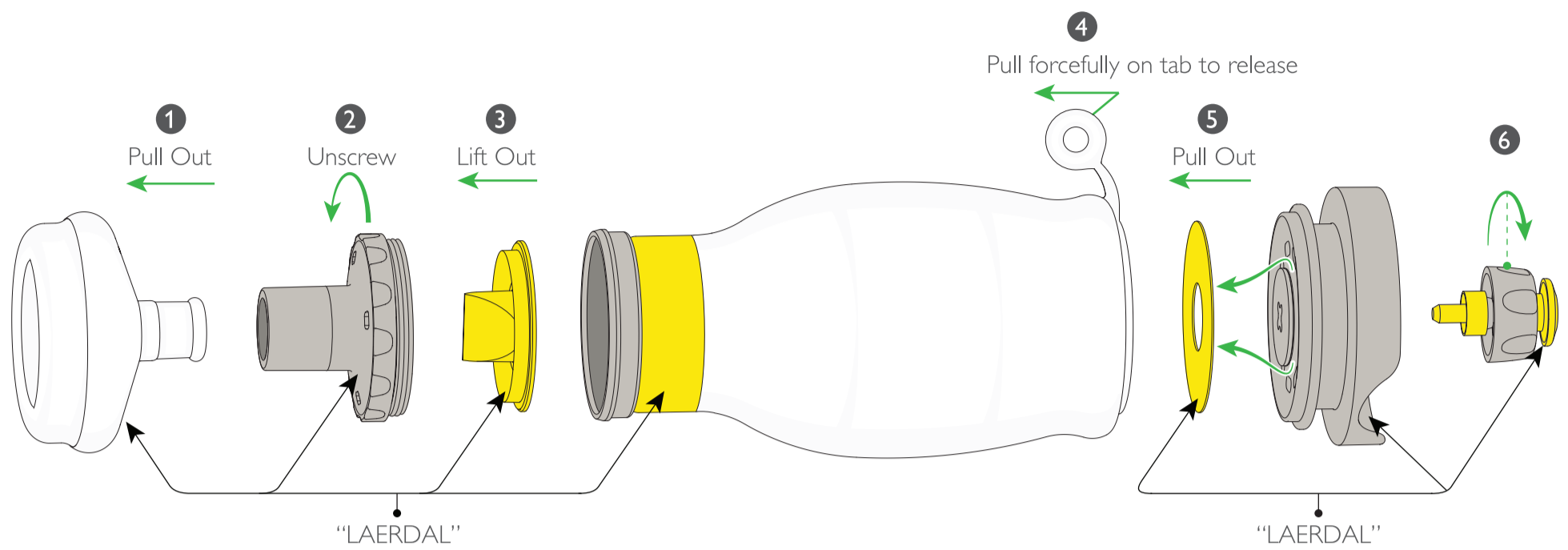
Meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators – Particular requirements for operator-powered resuscitators.

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

## Reprocessing instructions

### 1. Product overview

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



**Caution**  
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 dismantle Upright before cleaning.</p>	<ol style="list-style-type: none"> <li>1 Wash all parts in a clean tray with clean water and mild soap.</li> <li>2 Use a scrub or brush to remove any soil.</li> <li>3 Rinse parts in clean water to remove all soil and soap.</li> <li>4 Repeat above steps until parts are clean.</li> </ol>	<div style="display: flex; align-items: center; justify-content: center;"> <div style="text-align: center;"> <p>100 °C 10 minutes</p> <p><b>Boiling*</b> Boil all parts in clean water for 10 min.</p> <p><small>*Validated at approximately sea-level pressure</small></p> </div> <div style="margin: 0 20px;">OR</div> <div style="text-align: center;"> <p>Steam 136 °C 10-20 minutes</p> <p><b>Autoclaving</b> Sterilize by steam autoclaving at 136 °C and 2.0 kg/cm<sup>2</sup> for 10-20min.</p> </div> </div>	<ol style="list-style-type: none"> <li>1 Dry all parts.</li> <li>2 Visually inspect each part for damage and cleanliness / mineral deposits.</li> <li>3 Remove damaged or unclean parts from service.</li> </ol>	<p>Reassemble Upright. Test using steps shown below.</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.
- 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>



**Caution**  
If any of the above tests fail: Dismantle Upright, inspect that components, reassemble Upright and repeat the complete "Testing before use" procedure (Section 3).