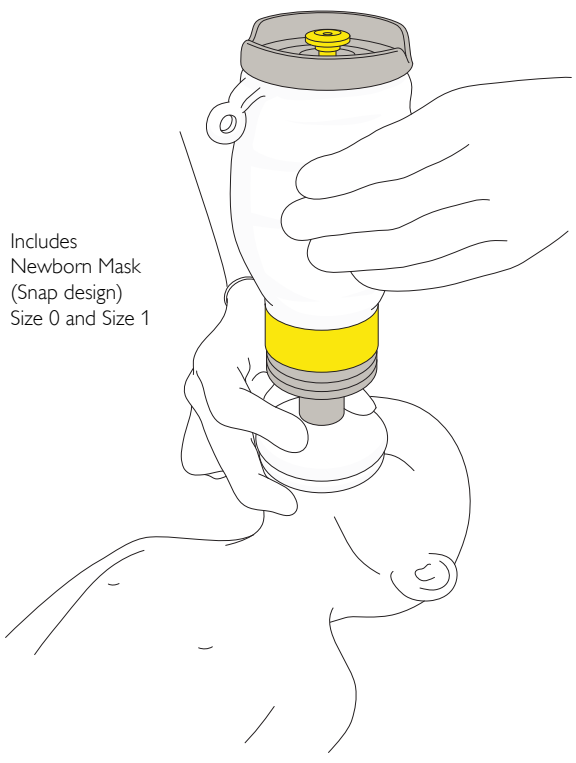
EN

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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helping save lives

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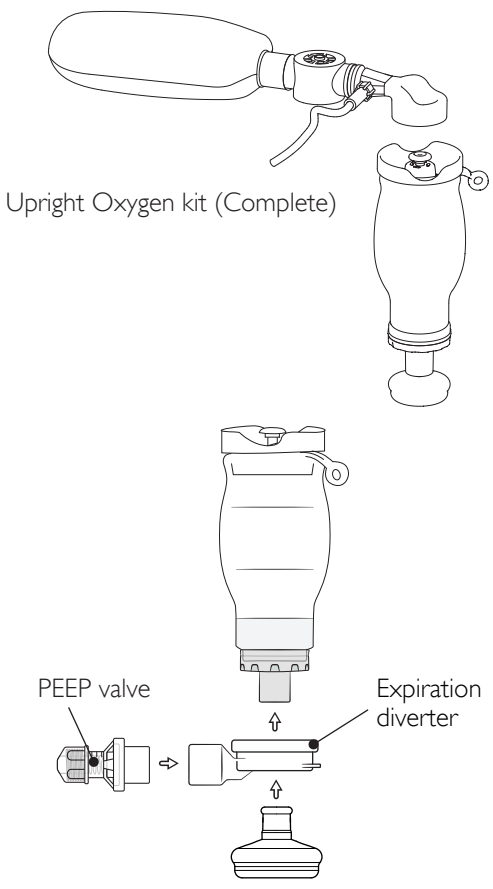
ACCESSORIES AND SPARE PARTS

Cat. no	Description
856156 **856157**	Newborn Mask - Snap design – Size 0* 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)



Upright Oxygen kit (Complete)

CLINICAL INDICATIONS

Device Description
The Upright Resuscutator 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 SpO_2, $EtCO_2$, 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.*
- *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.*
- *The Upright is not intended for use in delivery of medications, such as anaesthetic gases.*
- *The Upright patient port does not have a swivel function. Care should be taken when using with 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 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*

Notes

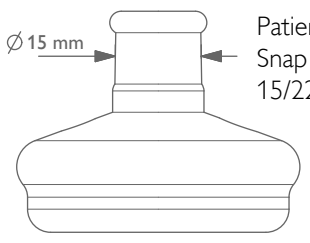
- *Should any serious malfunction, undesirable incident with, or deterioration in the functionality or performance of the device occur, contact Laerdal promptly. The competent authority where the incident took place and/or the device was used should also be notified.*
- *The use of third-party devices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

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.



Patient port on Newborn Mask
Snap design fit standard
15/22 mm connector

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_2O. 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_2 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_2O at 5 LPM
Inspiratory resistance		<0.5 cm H_2O 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.

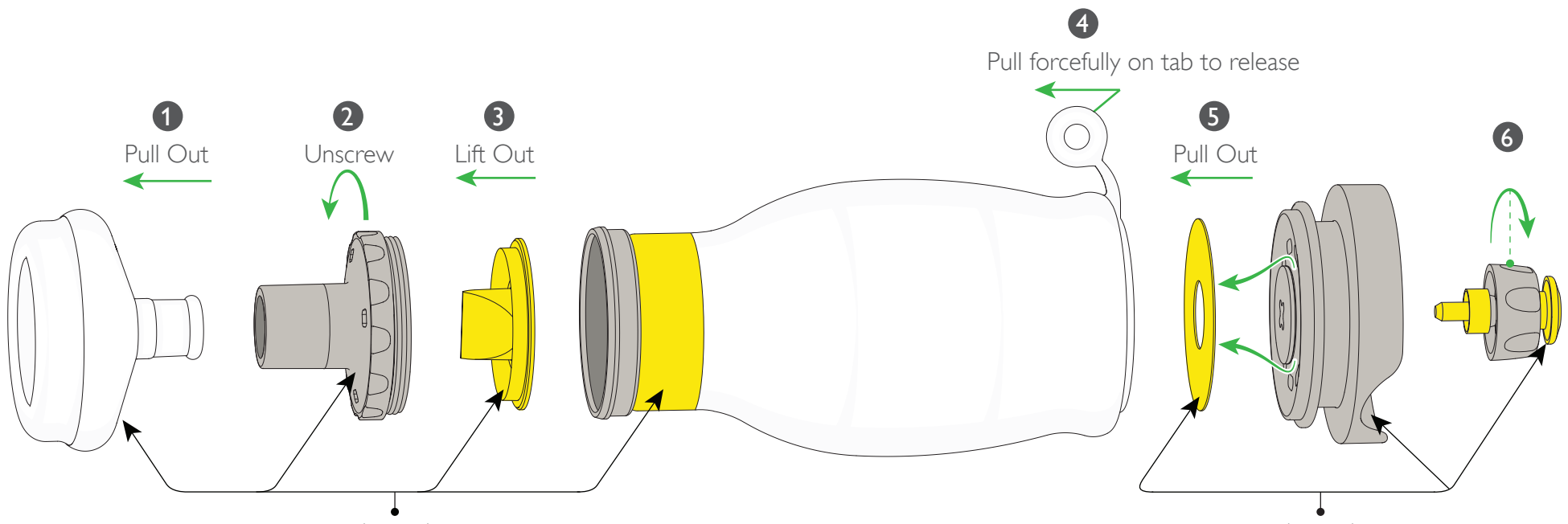
MD	Medical Device
CE 2460	This medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 for medical devices.
LATEX	Not made with natural rubber latex.

Laerdal Upright Resuscitator

Reprocessing instructions

1. Product overview

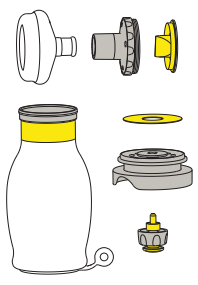
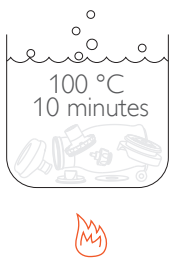
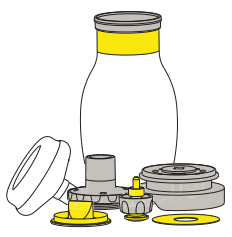
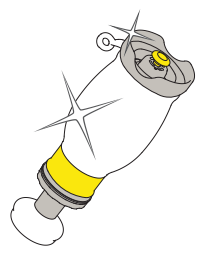
To dismantle, follow steps 1-6. To reassemble, follow the steps in reverse.



Caution

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

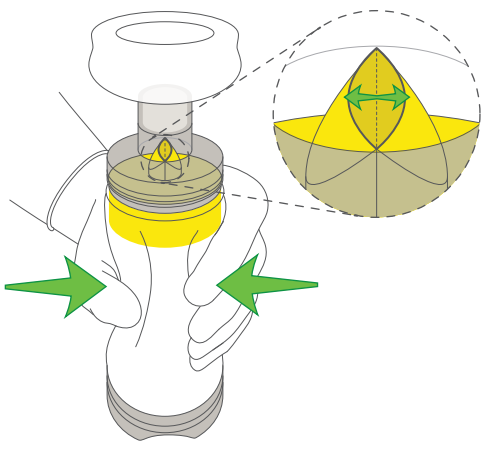
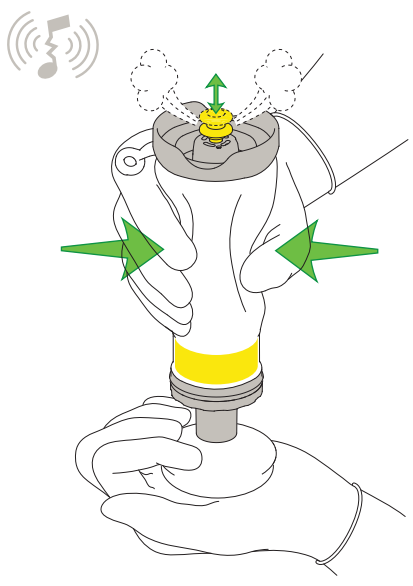
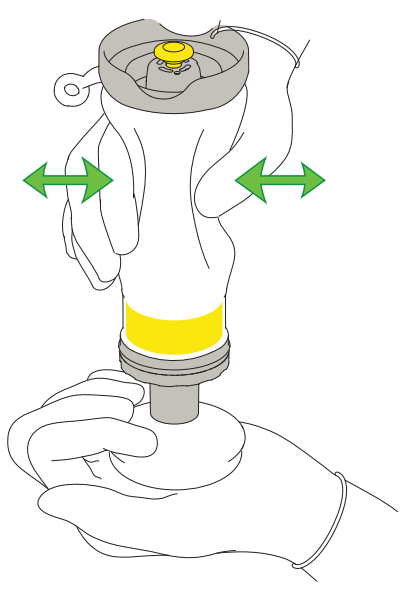
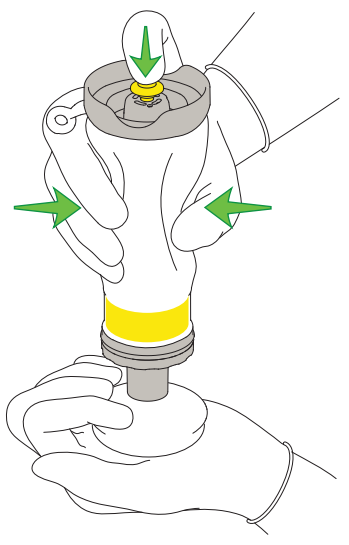
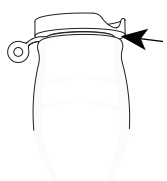
2. Cleaning and Disinfection procedure

1. Dismantle	2. Clean	3. Disinfect by one of the methods	4. Dry and Inspect	5. Assemble and Test
 Always disassemble before cleaning.	 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.*	 100 °C 10 minutes **Boiling*** Boil all parts in clean water for 10 min. *Validated at approximately sea-level pressure OR  Steam 136 °C 10-20 minutes **Autoclaving** *Sterilize by gravity displacement steam autoclaving at 136 °C and 2.0 kg/cm² for 10-20 min.*	 1. *Allow parts to air dry in a protected space.* 2. *Visually inspect each part for damage and cleanliness / mineral deposits.* 3. *Remove damaged or unclean parts from service.*	 Reassemble Upright. Test usings steps shown below.

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
 Squeeze the bag. Check that the yellow valve opens and closes with every squeeze.	 Seal the mask against your hand. Squeeze the bag forcefully. Check that air is released from the pressure release valve.	 Keep the mask sealed against your hand. Release the squeezed bag. Check that the bag re-expands without resistance.	 Check that the silicone bag's lip is not twisted or tucked under.  Keep the mask sealed against your hand. Press the pressure release valve down. Squeeze the bag and check that there is no leakage.

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).