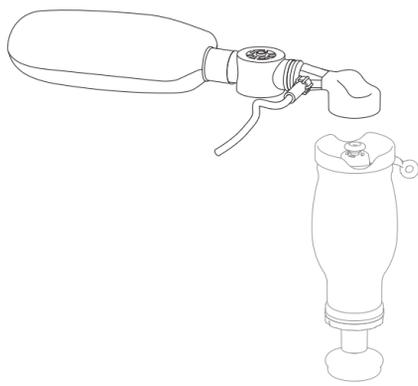


User Guide

Upright

OXYGEN KIT (COMPLETE)
REUSABLE



REF LGH-846151



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Date of issue: 2025-08



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CE 2460

20-20044 Rev D

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CLINICAL INDICATIONS*

Device Description

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

Indication for Use

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

Intended Use

The Upright Resuscitator with the Oxygen kit enables the delivery of oxygen-enriched air to the newborn.

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. 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

- This Oxygen Kit should only be used by persons who have received sufficient training in its use. Incorrect operation of the Oxygen Kit can be hazardous.
- Do not use the Oxygen Kit 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.
- Care should be taken when using the Upright on patients with severe pulmonary disease or severely immature lungs.
- 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 oxygen kit 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.

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 Reservoir bag and tubing cannot be sterilized.

Warranty

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

* Note: The following applies to the main device Upright Resuscitator, or alternatively to Upright with PEEP Resuscitator, when used with the Upright Oxygen Kit.

USING THE OXYGEN KIT

Upright can provide supplemental oxygen only when used with the Oxygen Kit.

Upright's pressure release valve can be operated as normal when the Oxygen Kit is attached.

The Oxygen kit may be reused provided proper cleaning and disinfection/sterilization procedures are performed between each patient use.

The Oxygen kit must be cleaned and disinfected before first patient use.

Do not attempt cleaning of Oxygen reservoir bag and tubing inside. If their inside is contaminated, they must be disposed of.

Assembly and disassembly of the Oxygen Kit is illustrated on page 2.

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

DELIVERED OXYGEN CONCENTRATION

Measured under room temperature conditions:

Oxygen flow [l/min]	20 ml tidal volume @ 60 breaths/minute		150 ml tidal volume @ 25 breaths /minute	
	without reservoir	with reservoir	without reservoir	with reservoir
2	40%	46%	52%	71%
4	52%	67%	63%	92%
6	58%	89%	73%	96%

Use with oxygen blender at Room Temperature:

Note

Oxygen reservoir bag must be used.

Setting the gas input supply flow of 4 LPM or more will ensure less than 5% dilution of the input gas with ambient air.

SAFETY WHEN USING OXYGEN

Build-up and transfer of high pressure to the patient is prevented as excess oxygen is vented to the atmosphere over the outlet valve.

If the reservoir bag remains flat during the whole ventilation cycle, it is a visual indication that no, or little supplemental oxygen is being provided.

When oxygen supply is insufficient, adequate ventilation volume is ensured by intake of ambient air through the Inlet valve.

In the presence of high oxygen concentrations there is danger from smoking or naked flames. Oil or grease must not be used with the resuscitator.

CLINICAL USE

Operating the Upright 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.

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.

SPARE PARTS

Cat. no	Description
846130	Oxygen Reservoir Bag and Tubing

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.

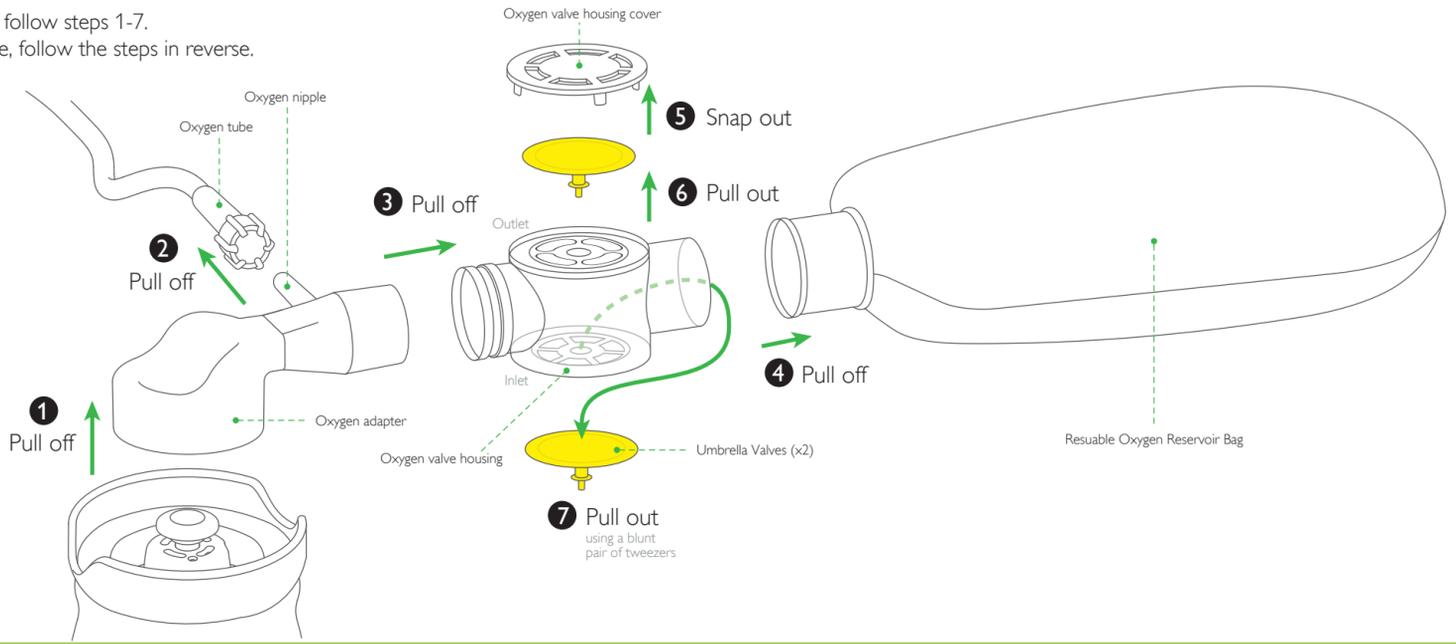
SPECIFICATIONS

Operating conditions	-18 °C to 50 °C 15% to 95% rH	
Storage conditions	-40 °C to 60 °C 15% to 95% rH	
External dimensions of Upright when using the Upright Oxygen kit (with Newborn Mask size 1, excluding tube)	Approximately 72mm x 375mm x 284mm	
Mass of Upright with Oxygen kit	Approximately 288 grams	
Materials	Hard plastic components	Polysulfone (PSU)
	Soft plastic components	Silicone rubber
	Spring	Stainless steel
	Oxygen Reservoir and Tubing	Polyvinyl chloride (PVC)
	Oxygen Reservoir Bag's Connector	Polycarbonate (PC)
Lifetime parameters	Shelf-life	5 years
	Expected Service Life	100 cycles of reprocessing

Reprocessing instructions

1. Product overview

To dismantle, follow steps 1-7.
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 provided with the Upright Oxygen Kit

2. Cleaning and Disinfection procedure

1. Disassemble	2. Clean	3. Disinfect by one of the methods	4. Dry and Inspect	5. Assemble and Test
<p>Always disassemble before cleaning.</p> <p>Hard components and yellow valves:</p>	<p>Follow the same procedures as for Upright components.</p>	<p>Boiling</p> <p>100 °C 10 minutes</p> <p>OR</p> <p>Autoclaving</p> <p>Steam 136 °C 10-20 minutes</p> <p>Follow the same procedures as for Upright components.</p>	<p>1. Dry all parts.</p> <p>2. Visually inspect each part for damage and cleanliness / mineral deposits.</p> <p>! Caution Remove damaged or unclean parts from service.</p>	<p>1. Reassemble the Oxygen Kit.</p> <p>2. Test the Oxygen Kit with Upright using steps shown below.</p> <p>Note Improper assembly of the Upright Oxygen kit after reprocessing may affect performance.</p>
<p>Reservoir bag and oxygen tube:</p>	<p>If the inside of the oxygen tube or the oxygen reservoir bag has become soiled, they must be discarded.</p> <p>For outside-surface soiling:</p> <p>Wash outside surfaces with clean water and mild soap.</p>	<p>For reservoir bag and oxygen tube go directly to 4. Dry and Inspect.</p> <p>! The Reservoir Bag and Oxygen Tube cannot withstand high temperatures.</p>		

! Cautions

- The oxygen kit is not provided sterile. The oxygen kit 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.
- The use of cleaning and disinfection procedures not described in this section may have adverse effects on the Upright oxygen kit material and/or performance and may not be effective for disinfecting the parts.

3. Testing before use

1. Oxygen adaptor sealing	2. Outlet valve to ambient	3. Inlet valve from ambient
<p>1. Center the oxygen adaptor with Upright's top and one of its U-shaped edges.</p> <p>2. Press hard down into Upright</p> <p>3. Check that the adaptor's neck is centered in the U-shape, without touching its side edges.</p> <p>4. Seal the oxygen-nipple with a finger and seal the open connector-end with your hand.</p> <p>5. Squeeze Upright's bag fully, and release.</p> <p>6. Check that the bag does not re-expand quickly.</p>	<p>1. Attach the oxygen valve housing to the oxygen adaptor.</p> <p>2. Fill the reservoir bag with air by using Upright as a pump.</p> <p>3. Attach the oxygen valve housing to the oxygen adaptor.</p> <p>4. Seal the oxygen nipple with a finger.</p> <p>5. Compress the filled reservoir bag rapidly with your hand.</p> <p>6. Check visually that the outlet valve opens and bleeds off excessive air.</p>	<p>1. Seal the oxygen nipple with a finger.</p> <p>2. Squeeze Upright's bag several times.</p> <p>3. Check that the reservoir bag empties completely</p> <p>4. Squeeze the Upright bag fully and then release quickly.</p> <p>5. Check visually that the inlet valve opens and draws in ambient air.</p>

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