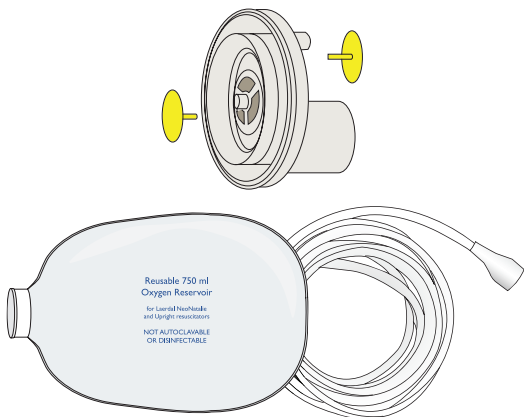


# NeoNatalie Resuscitator Oxygen kit

## User Guide



**REF** Cat.No. 846141

**QTY** 1 each

This oxygen kit is an accessory to the Laerdal NeoNatalie Resuscitator; Cat. No. 846040. The NeoNatalie Resuscitator's User Guide applies fully also when used with this NeoNatalie Resuscitator Oxygen kit User Guide.

## CLINICAL INDICATIONS

### **Indication for Use**

The NeoNatalie Resuscitator (NNR) 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 NeoNatalie Resuscitator with the Oxygen kit enables the delivery of oxygen-enriched air to the newborn.

### **Intended Users**

The NNR is intended to be used by healthcare professionals trained in delivering ventilatory support.

### **Clinical Benefits**

Positive impact on clinical outcome, by respiratory support that reduces probability of adverse outcomes, such as morbidity and mortality caused by hypoxia.

### **Known Side Effects**

Oxygen Toxicity

### **Contraindications**

No known contraindications for use.

# IMPORTANT INFORMATION

Read this User Guide and become familiar with the operation and maintenance of the product 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

Important information about the product or its operation.

Please ensure that following precautions are taken to ensure that the resuscitator functions properly during use.



## Warnings

- *This resuscitator should only be used by persons who have received sufficient training in its use. Incorrect operation of the resuscitator can be hazardous.*
- *This resuscitator should not be used in poisonous or hazardous atmospheres.*
- *Do not use the resuscitator if you have any reason to be concerned about its functionality.*
- *Care should be taken when using the NNR on patients with severe pulmonary disease or severely immature lungs.*
- *Care should be taken when using the NNR on patients with severe patient 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.*



## Cautions

- Use only NeoNatalie Resuscitator parts from a Laerdal authorized source with this resuscitator.
- The resuscitator may be reused provided proper cleaning and sterilization procedures are performed between each patient use. The resuscitator must be cleaned and disinfected before first patient use.
- This resuscitator can provide supplemental oxygen only when used with the Oxygen Kit. The NeoNatalie Resuscitator is not supplied with the Oxygen Kit and its User Guide (sold separately).
- The resuscitator is not intended for use in an ambulance.
- Use only NeoNatalie Resuscitator parts from a Laerdal authorized source with this resuscitator.
- The hard plastic components of the resuscitator are incompatible with polar solvents such as ethanol and isopropyl alcohol.

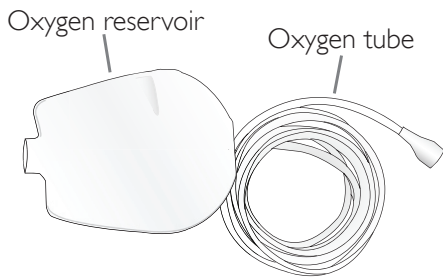
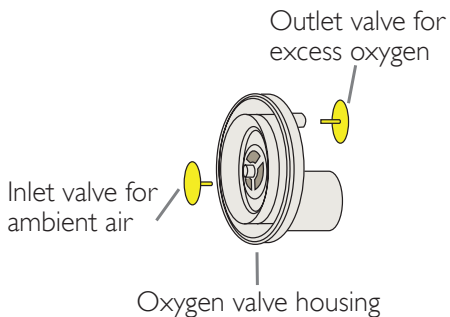


## Notes

- Note that the patient port connector does not have a swivel function which can reduce the flexibility of the user to reposition the resuscitator when connected to an advanced 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.

## ITEMS INCLUDED / OVERVIEW

### Directions for Use – Oxygen kit



Oxygen reservoir bag with tubing

## SAFETY WHEN USING OXYGEN

1. Build-up and transfer of high pressure to the patient is prevented since excess  $O_2$  is vented to atmosphere over the outlet membrane of the Intake Valve.
2. When  $O_2$  supply is insufficient, adequate ventilation volume is ensured by intake of ambient air over the intake membrane of the Intake Valve.
3. 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.
4. A Reservoir Bag that stays flat during the whole ventilation cycle is a visual indication that none, or little supplemental  $O_2$  is being provided.

## GENERAL HYGIENE

Before first-time use, dis-assemble the oxygen kit and wash and clean as described for in Section 10.

## CHECK BEFORE EACH USE

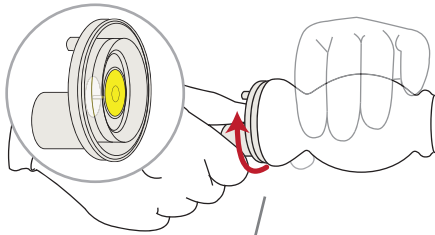
1. Attach the Oxygen valve housing onto the resuscitator's inlet valve.
2. Fill the Reservoir Bag with ambient air by holding the Reservoir Bag over the patient port connector pressing with your thumb on the reservoir bag connector. Ensure tight seal between the patient port and Reservoir Bag. Compress the bag with your other hand several times to inflate the reservoir bag with ambient air.
3. Attach the filled Reservoir Bag to the Oxygen valve housing.
4. Compression of the Reservoir Bag and visual rise of the outlet Flap Valve confirms that the Reservoir Valve efficiently vents excessive gas to atmosphere.
5. Perform several compression-release cycles on the ventilation bag until the Reservoir Bag is flat and empty. Rapid re-expansion of the ventilation bag after flattening of the Reservoir Bag confirms that the Reservoir Valve efficiently lets in ambient air.

## USING THE OXYGEN KIT

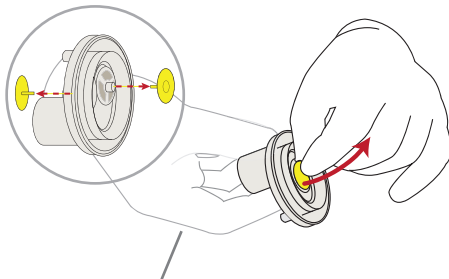
1. Screw the Oxygen valve housing onto the resuscitator's inlet valve.
2. Attach the oxygen tube to the oxygen valve housing and the oxygen source, for higher oxygen concentrations.
3. Attach the reservoir bag to the oxygen valve housing, for higher oxygen concentrations.
4. See Section 14 for oxygen concentrations.

## DIS-ASSEMBLING THE OXYGEN KIT

Dis-assemble the resuscitator before performing the cleaning procedure.



Unscrew the rear end of the intake valve housing from the bag.



Remove both oxygen umbrella valves from the rear end of the intake valve housing.



## CLEANING AND DISINFECTION

After each use, dis-assemble and clean the oxygen kit parts:

- Wipe off the oxygen tube and oxygen reservoir with soapy water only on the outside surfaces. Rinse the outside surfaces in clean water.
- Wash and scrub the housing and valve parts in soapy water.
- Rinse in clean water.
- The oxygen valve parts may be sterilized by autoclaving or disinfected as described in the NeoNatalie Resuscitator User Guide. Note that the oxygen reservoir and oxygen tube cannot withstand high temperatures.
- Visually inspect each part for damage and cleanliness / mineral deposits. Remove damaged or unclean parts from service. See NeoNatalie Resuscitator User Guide for descaling instructions..

### **Warning**

*Discard Oxygen Reservoir Bag and Oxygen Tube if interior surfaces have been contaminated.*

### **Note**

*The Reservoir bag and tubing cannot be sterilized.*

## RE-ASSEMBLING THE OXYGEN KIT

To re-assemble the Oxygen kit, perform the steps described under Section 9 - in reverse.

## SPECIFICATIONS

Delivered oxygen concentration measured at approx. 23 °C:

	20 ml tidal volume 60 breaths/min		150 ml tidal volume 25 breaths/min	
Oxygen flow	Without reservoir bag	With reservoir bag	Without reservoir bag	With reservoir bag
2 LPM	52 %	71 %	56 %	84 %
4 LPM	60 %	97 %	58 %*	99 %**
6 LPM	58 %	98 %	60 %	94 %

\* At -18 °C: 53%. At 50 °C: 47%

\*\* At -18 °C: 66%. At 50 °C: 88%

### Conditions

Operating Conditions	Temperature: -18 °C to 50 °C
Storage Conditions	Temperature: -40 °C to 60 °C
Weight	Approx. 80 grams
Resuscitator with oxygen kit	Approx. 440 mm x 70 mm x 180 mm

### Lifetime Parameters






Shelf-life	3 years
Expected Service Life	50 cycles of reprocessing

### Material Chart

Hard plastic components	Polysulfone (PSU)
Reservoir bag and oxygen tube	Polyvinylchloride (PVC)
Valves	Silicones (SI)

## REGULATORY

### Symbol Glossary

	Medical Device
	This medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 for medical devices.
	Caution: Federal law restricts this device to sale by, or on the order of a physician (US).
	Not made with natural rubber latex
	Single-use symbol

### Warranty

Refer to the Laerdal Global Warranty for terms and conditions.  
For more information visit [www.laerdal.com](http://www.laerdal.com).

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