NeoNatalie Resuscitator Oxygen kit

Directions for Use





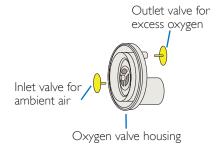
This oxygen kit is an accessory to the Laerdal NeoNatalie Resuscitator, Cat. No. 846040. The NeoNatalie Resuscitator's Directions for Use applies fully also when used with this NeoNatalie Resuscitator Oxygen kit Directions for Use.

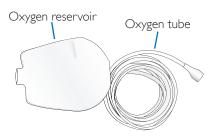
1 Intended Use

The NeoNatalie Resuscitator with the Oxygen kit enables the delivery of oxygen-enriched air to the newborn. The oxygen kit may be reused provided proper cleaning and sterilization or disinfection procedures are performed between each patient use.

2 Items Included / Overview

• Directions for Use - Oxygen kit





Oxygen reservoir bag with tubing

3-4

No amendments. Refer to the NeoNatalie Resuscitator's Directions for Use

5 Safety when using oxygen

- Build-up and transfer of high pressure to the patient is prevented since excess O₂ is vented to atmosphere over the outlet membrane of the Intake Valve.
- When O₂ supply is insufficient, adequate ventilation volume is ensured by intake of ambient air over the intake membrane of the Intake 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.
- A Reservoir Bag that stays flat during the whole ventilation cycle is a visual indication that none, or little supplemental O₂ is being provided.

6 General Hygiene

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

7 Check Before Each Use

- 1. Attach the Oxygen valve housing onto the resuscitator's inlet valve.
- 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

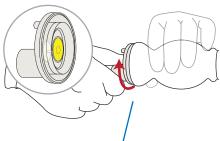
- and Reservoir Bag. Compress the bag with your other hand several times to inflate the reservoir bag with ambient air.
- 3. Attach the filled Reservoir Bag to the Oxygen valve housing.
- 4. Compression of the Reservoir Bag and visual rise of the outlet Flap Valve confirms that the Reservoir Valve efficiently vents excessive gas to atmosphere.
- 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.

8 Using the Oxygen kit

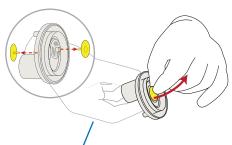
- 1. Screw the Oxygen valve housing onto the resuscitator's inlet valve.
- Attach the oxygen tube to the oxygen valve housing and the oxygen source, for oxygen concentrations of approximately 35 %.
- 3. Attach the reservoir bag to the oxygen valve housing, for oxygen concentrations of approximately 75%.

9 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.

10 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 by boiling as described in the NeoNatalie Resuscitator Directions for Use, Section 10.
- The reservoir bag and tubing can only be cold sterilized.
 - Note:The Reservoir bag and tubing cannot be autoclaved or boiled.
- The Reservoir Bag must be dried by blowing air into the Reservoir Bag opening.

11 Re-assembling the Oxygen kit

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

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No amendments. Refer to the NeoNatalie Resuscitator's Directions for Use.

14 Technical Information

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%

Specifications

Materials:

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

Weight:

Approx. 80 grams

Dimensions:

Resuscitator with oxygen kit: Approx. 440 mm \times 70 mm \times 180 mm



This product is in compliance with the essential requirements of Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC.

^{**} At -18 °C: 66%. At 50 °C: 88%

Global Warranty

See www.laerdal.com

Manufactured by Laerdal Medical AS, Tanke Svilandsgate 30 P.O. Box 377, 4002 Stavanger, Norway

Tel. +47 51 51 17 00. Fax +47 51 52 35 57. E-mail: Laerdal.norway@laerdal.no

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