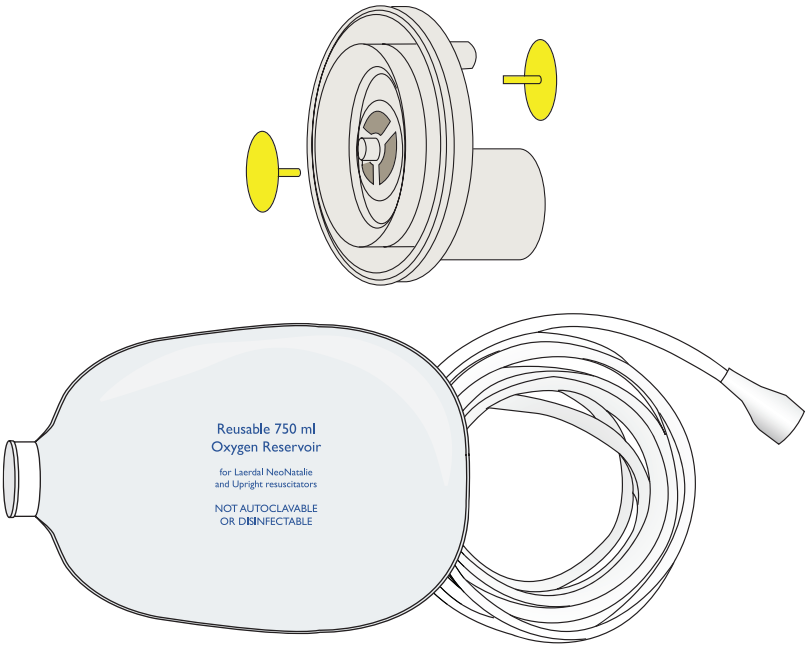
EN

NeoNatalie Resuscitator

Oxygen Kit

REUSABLE

User Guide



REF Cat.No. 846141 **QTY** 1 each

This Oxygen Kit is an accessory to the Laerdal NeoNatalie Resuscitator, Cat. No.846040.

www.laerdalglobalhealth.com

Laerdal
helping save lives

Contents

Clinical Indications	4
Important Information	5
Items Included	6
Attach Oxygen Valve Housing to Resuscitator	7
Function Test	8
Clinical Use	10
Disassembling and Reassembling	11
Cleaning and Disinfection	12
Specifications	13

Clinical Indications

Note

The following applies to the main device NeoNatalie Resuscitator, when used with the NeoNatalie Resuscitator Oxygen Kit.

Device Description

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

Indication for Use

The NeoNatalie Resuscitator 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 NeoNatalie Resuscitator 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.

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

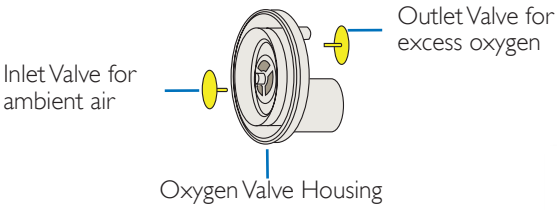
- *This Oxygen Kit should only be used by persons who have received sufficient training in its use. Incorrect operation of the Oxygen Kit can be hazardous. Do not use the Oxygen Kit if you have any reason to be concerned about its functionality.*
- *Care should be taken when using the NeoNatalie Resuscitator on patients with severe pulmonary disease or severely immature lungs.*
- *The NeoNatalie Resuscitator is not intended for use in delivery of medications, such as anaesthetic gases.*

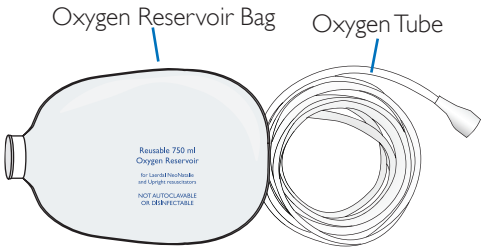
⚠ Cautions

- *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.*

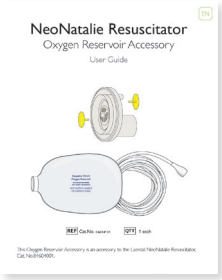
Note

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.





Oxygen Reservoir Bag with Tubing



User Guide

⚠ Caution

Use only Oxygen Kit (NeoNatalie) parts from a Laerdal authorized source with this resuscitator.

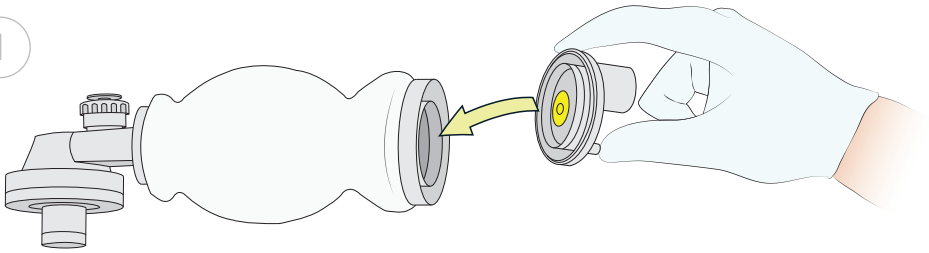
Spare Parts

Cat. no	Description
846130	Oxygen Reservoir Bag and Tubing (NeoNatalie)

Safety When Using Oxygen

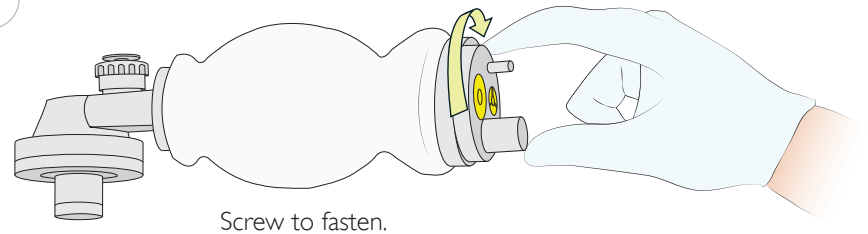
1. Build-up and transfer of high pressure to the patient is prevented since excess O_2 is vented to atmosphere over the Outlet Valve of the Oxygen Kit.
2. When O_2 supply is insufficient, intake of ambient air for ventilation is afforded by the Inlet Valve of the Oxygen Valve Housing.
3. An Oxygen Reservoir Bag that stays flat during the whole ventilation cycle is a visual indication that none, or little supplemental O_2 is being provided.
4. 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.

1



Place the Oxygen Valve Housing onto the Inlet Valve.

2

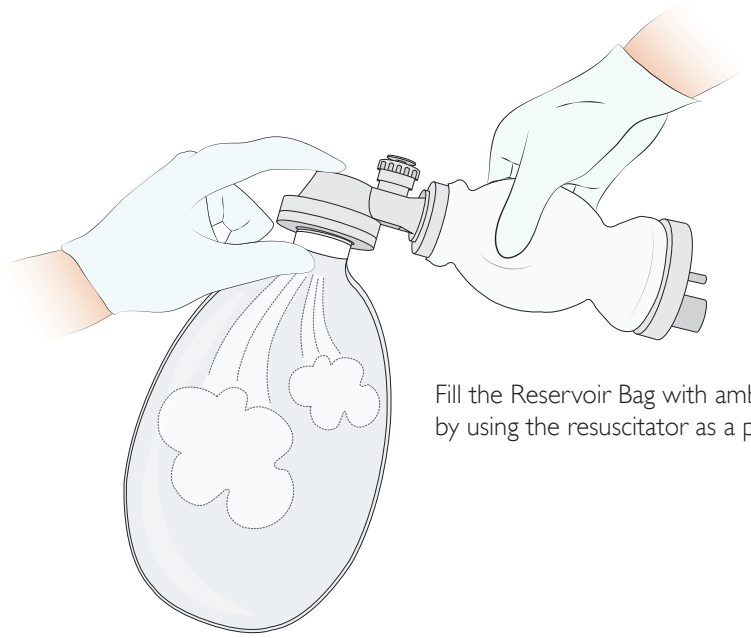


Screw to fasten.

Function Test

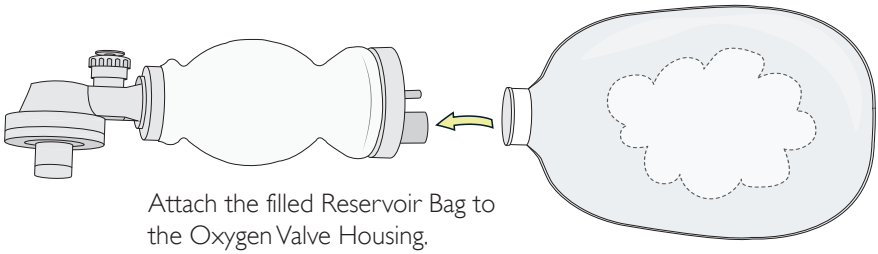
Check before each use.

1



Fill the Reservoir Bag with ambient air by using the resuscitator as a pump.

2

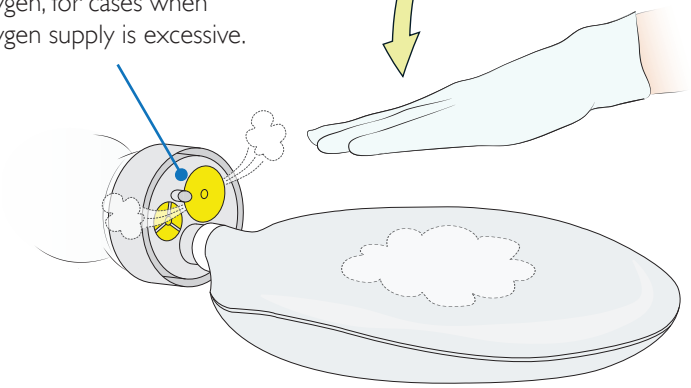


Attach the filled Reservoir Bag to the Oxygen Valve Housing.

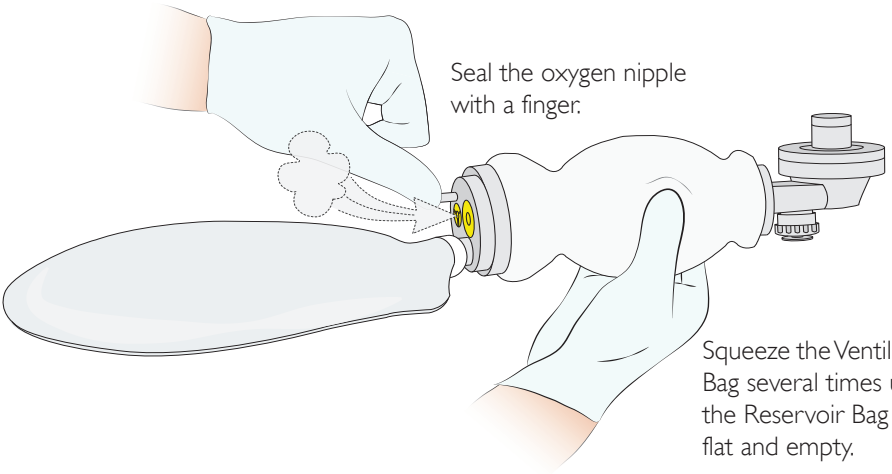
3

Check visually that the Outlet Valve opens and bleeds off excessive air/ oxygen, for cases when oxygen supply is excessive.

Compress the filled Reservoir Bag rapidly with your hand.



4



Squeeze the ventilation bag fully and then release quickly. Rapid re-expansion of the Ventilation Bag confirms that the Inlet Valve efficiently draws in ambient air, for cases when oxygen supply is inadequate.

Using the Oxygen Kit

The Oxygen Valve Housing and the Inlet and Outlet valves must be cleaned and disinfected before first patient use.

The Oxygen Kit may be reused provided proper reprocessing procedures are performed between each patient use.

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

Note

The oxygen source should be able to be adjusted to provide a flow relevant to the NeoNatalie Resuscitator.

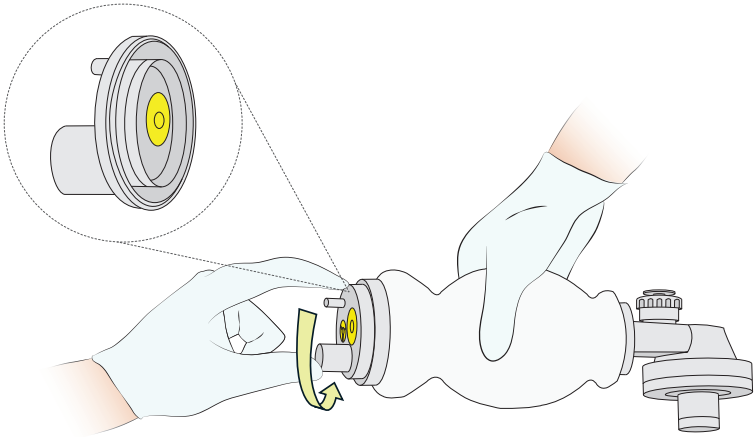
1. Screw the Oxygen Valve Housing onto the resuscitator's Inlet Valve.
2. Attach the oxygen tube to the Oxygen Valve Housing and the oxygen source. See *Technical Information* section for oxygen concentrations at typical oxygen flow rates.
3. For higher oxygen concentrations, attach the reservoir bag to the Oxygen Valve Housing.

If any components are loose, then tighten or reassemble the device and test in accordance with page 8-9.

Disassembling the Oxygen Kit

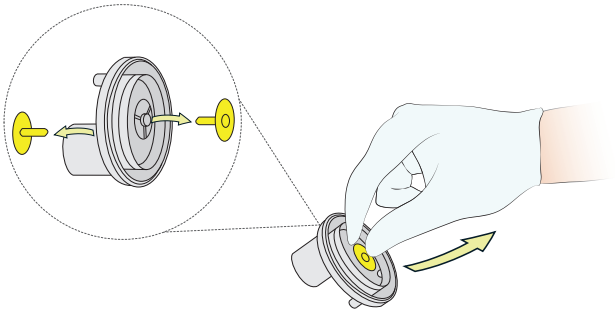
Disassemble the Oxygen Valve before performing the cleaning procedure.

1



Unscrew the Oxygen Valve Housing from the bag.

2



Remove Inlet and Outlet Valves from the Oxygen Valve Housing.

Reassembling the Oxygen Kit

Discard any damaged components.
To reassemble the Oxygen Kit, perform the steps described under *Disassembling the Oxygen Kit* section in reverse.

Cleaning and Disinfection

After each use, disassemble and clean the Oxygen Kit parts.

Oxygen Valve Housing and yellow Inlet and Outlet Valves

Cleaning

1. Manual Cleaning: Wash all parts in a clean tray with clean water and mild soap. Use a scrub or brush to remove any soil.
2. Rinsing after cleaning: Rinse parts thoroughly in clean water to remove all soil and soap.
3. Inspect to ensure that no soil is visible. If necessary, manual washing may be repeated.
4. Allow the parts to dry completely.
5. Continue with disinfection as described.

Disinfection

The Oxygen Valve Housing and the yellow Inlet and Outlet Flap Valves can be disinfected by:

1. Steam Autoclaving*. Autoclave with distilled water for 10 minutes at 136 °C.	OR	2. Boiling or Steaming Boil* or Steam with clean water at 100 °C for 10 minutes
*Prevacuum-pulse autoclave		*Validated at approximately sea-level pressure

Drying and Inspection

1. Dry all parts.
2. Visually inspect each part for damage and cleanliness/mineral deposits.
3. Remove damaged or unclean parts from service.

Oxygen Reservoir Bag and Tubing

- Wipe off the Oxygen Reservoir Bag and Oxygen Tube with soapy water only on the outside surfaces. Rinse the outside surfaces with clean water.
- Dry all parts.
  Visually inspect for damage and cleanliness.
- Remove damaged or unclean parts from service.

Notes

The Oxygen Reservoir Bag and Oxygen Tube cannot be disinfected.

Warning

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

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

Symbol Glossary

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

Delivered oxygen concentration

Measured at approx. 23 °C (73 °F)

20 ml tidal volume 60 breaths/min		
Oxygen flow	Without reservoir bag	With reservoir bag
2 LPM	54%	56%
4 LPM	58%	84%
6 LPM	64%	91%

Use with oxygen blender at Room Temperature

Note

Oxygen reservoir bag must be used.

Setting the gas input supply flow of 6 LPM or more will ensure less than 10% dilution of the input gas with ambient air

Specifications

Conditions	
Operating Conditions	- 18 °C to 50 °C 15% to 95% rH
Storage Conditions	- 40 °C to 60 °C 15% to 95% rH
Resuscitator with Oxygen Kit Dimensions	Approx. 440 mm x 70 mm x 180 mm
Weight	Approx. 80 grams
Oxygen Reservioir Bag volume	Approx. 750 ml
Lifetime Parameters	
Shelf-life	5 years
Expected Service Life	50 cycles of reprocessing
Material Chart	
Reservoir Bag	Polyvinylchloride (PVC) and Polycarbonate (PC).
Oxygen Tube	Polyvinylchloride (PVC)
Valve housing	Polysulfone (PSU)
Valves	Silicone Rubber (SI)

Laerdal Global Warranty

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

© 2025 Laerdal Medical AS. All rights reserved.
NeoNatalie Resuscitator, Newborn - Reusable, the Laerdal Logo, and "helping save lives" are all trademarks of Laerdal Medical.

Date of Issue: 2025-04

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

20-19670 Rev C

CE 2460

www.laerdalglobalhealth.com

Laerdal
helping save lives