

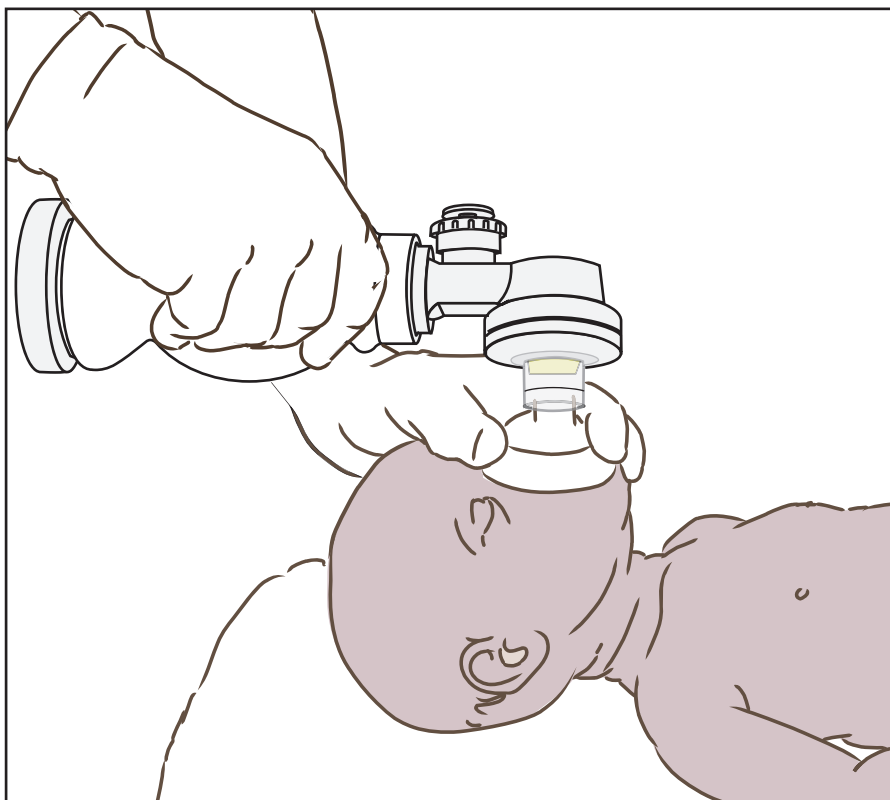
NeoNatalie Resuscitator

Newborn - Reusable

Directions for Use

REF Cat.No. 846040

QTY 1 each



Please read these Directions for Use carefully to become thoroughly familiar with proper operation and maintenance of this resuscitator before using it.

Contents

1	Intended Use	2
2	Items Included (Main Unit)	3
3	Accessories and Spare Parts	3
4	Resuscitator Overview	4
5	Cautions and Warnings	4
6	General Hygiene	5
7	Check Before Each Use	5
8	Using the Resuscitator	7
9	Dis-assembling the Resuscitator	8
10	Cleaning After Use	10
11	Re-assembling the Resuscitator	11
12	Storage	11
13	Glossary of Symbols	11
14	Technical Information	11

There is an urgent need to train millions of birth attendants in developing countries in effective newborn resuscitation techniques in order to achieve the UN Millennium Development Goal 4 of reducing infant and child mortality by 2/3 from 1990 to 2015. Laerdal hopes to contribute to such widespread training by providing the NeoNatalie Resuscitator and other NeoNatalie products on a not-for-profit basis to developing countries.

NeoNatalie is a trademark of Laerdal Medical AS or its affiliates. Ownership and all rights reserved.

1 Intended Use

This resuscitator is a self-inflating, manual resuscitator intended for newborns and infants (up to 5 kg) who require respiratory support. The resuscitator provides positive pressure ventilation of the lungs when used with a face mask.

The resuscitator may be reused provided proper cleaning and sterilization or disinfection procedures are performed between each patient use.



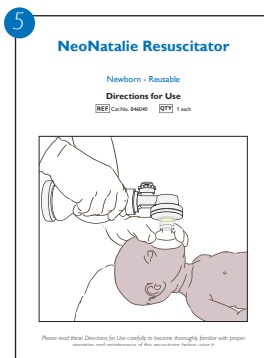
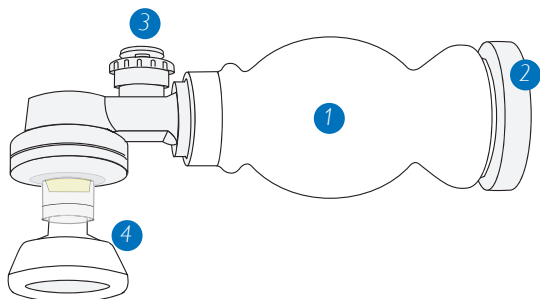
Note: This resuscitator is also suitable for ventilation training on a realistic resuscitation training manikin, such as the NeoNatalie Newborn Simulator, which is provided for the "Helping Babies Breathe" project.



Note: This resuscitator can provide supplemental oxygen only when used with the accessory oxygen kit.

2 Items Included (Main Unit)

Remove the resuscitator from its packaging and check that the product is complete.



Ensure that the following items are included:

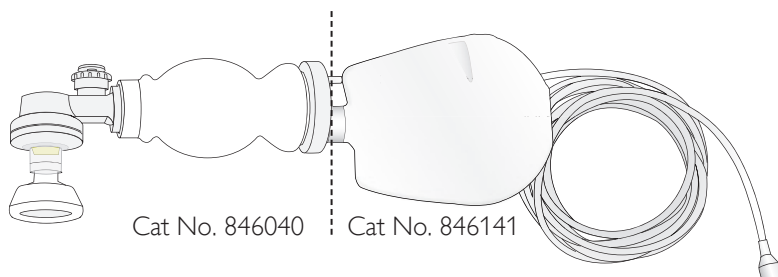
- ① Compressible, self-inflating ventilation bag
- ② Inlet valve for ambient air
- ③ Patient valve with a pressure release valve
- ④ Two circular masks, sizes 0 and 1
- ⑤ Directions for Use

Cat. no	Description
846040	NeoNatalie Resuscitator; Newborn - Reusable

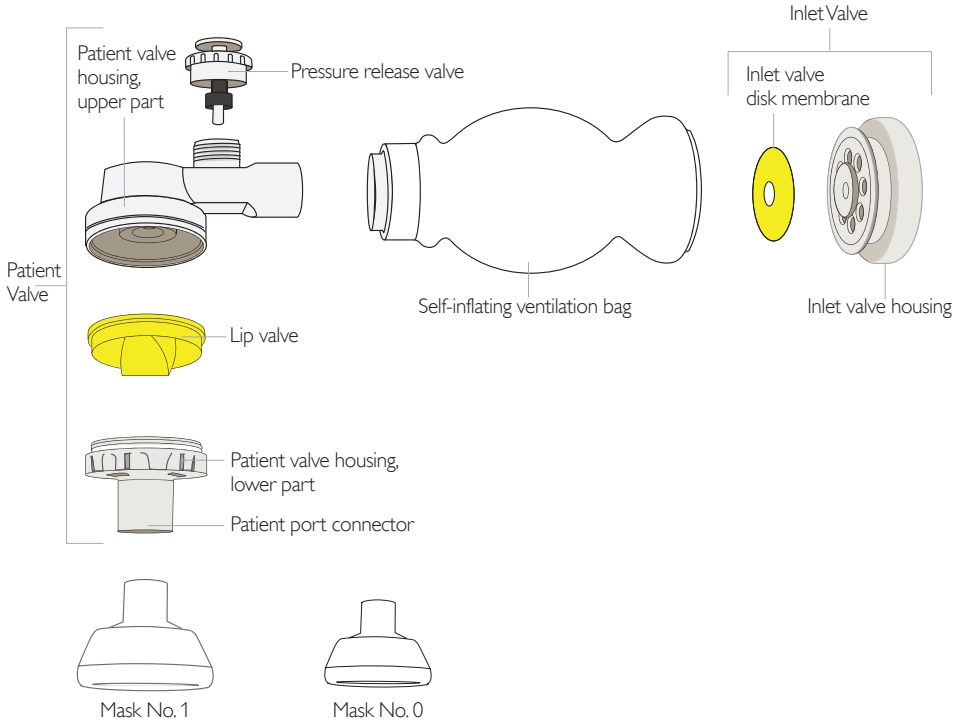
3 Accessories and Spare Parts

Cat. no	Description
846141	Oxygen kit (complete): Oxygen Reservoir Bag, Valve and Tubing (NeoNatalie)
846131	Oxygen Reservoir Bag and Tubing (NeoNatalie)
846145	Valves/Membranes, Complete set (NeoNatalie)
846136	Silicone Mask no. 0 (NeoNatalie) Qty. 10*
846137	Silicone Mask no. 1 (NeoNatalie) Qty. 10*

*Masks are bulk packed: 10 masks in 1 polybag.







4 Resuscitator Overview



5 Cautions and Warnings

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

-  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.
-  Use only NeoNatalie Resuscitator parts with this resuscitator.

6 General Hygiene

During Training

The resuscitator must be kept clean at all times:

- Wipe all surfaces clean with a wet cloth before and after each training session.
- If necessary use warm, soapy water. Wash hands between users.

For Patient Use

After each use, dis-assemble the resuscitator:

- Wash and scrub all parts in soapy water.
- Rinse in clean water.
- Sterilize or disinfect by using one of the methods as described in the section 10 - Cleaning After Use.



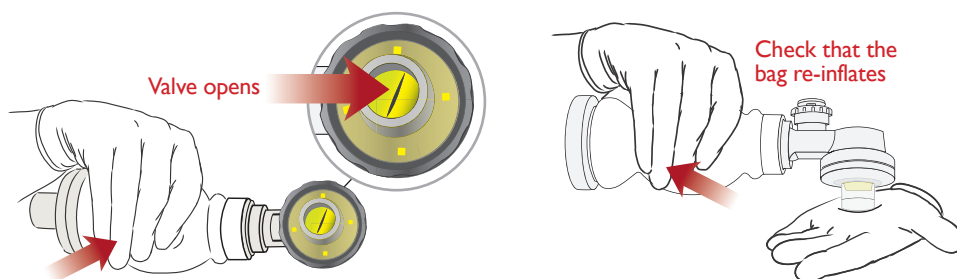
Note: This product must be cleaned before first patient use. See section 10 - Cleaning After Use.

7 Check Before Each Use

To ensure proper functioning of the resuscitator; check the following functions before each use:

1. To ensure that air is delivered to the patient

Squeeze the bag and ensure the yellow lip valve opens with each squeeze. This indicates that air can be successfully delivered to a patient.

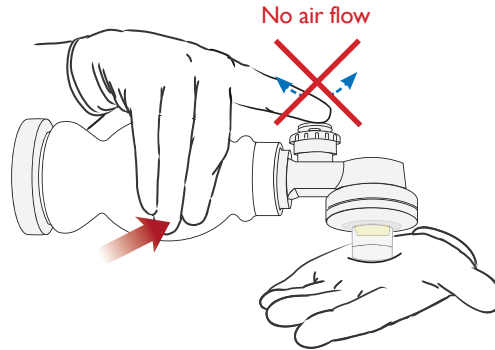


Squeeze the bag. Keeping the bag squeezed, seal the patient port connector against the palm of one hand.

Release the bag, checking that it re-inflates quickly after release.

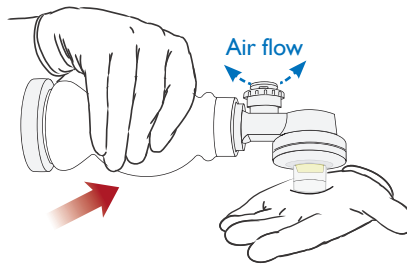
2. Check the resuscitator for leakage

Seal the patient port connector to the palm of one hand. With the other hand press the index finger against the pressure release valve and squeeze the bag to ensure that no air escapes through the pressure release valve or from the bag.



3. Check the pressure release valve

Seal the patient port connector against the palm of one hand. With the other hand squeeze the bag and ensure that excessive air escapes through the pressure release valve.

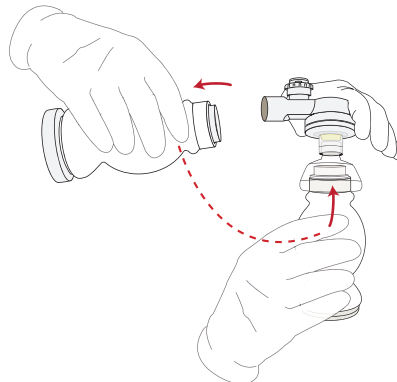


4. Checking patient exhalation

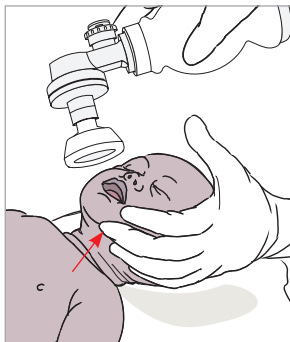
Connect a patient mask to the patient port connector. Remove the bag from the patient valve. Press the bag into the mask opening to form a seal. Squeeze the bag to mimic the baby's lungs and check that the bag can be squeezed without resistance.



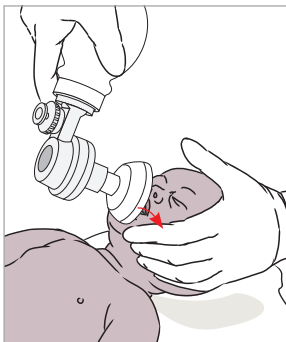
Note: If the resuscitator fails any of these tests remove the resuscitator from use. Dismantle the resuscitator, replace any visually damaged components, and re-assemble and re-test the resuscitator.



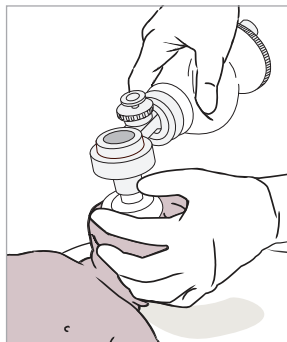
8 Using the Resuscitator




1. Slightly extend the patient's head and neck.





2. Cover the patient's mouth and nose completely with the mask. Press downwards to create a seal between the mask and the patient's face.




3. Squeeze the bag until chest rise is observed. Repeat this procedure at the recommended rate.

 *Note: Safety valve: The resuscitator has a pressure release (pop-off) valve which releases air when pressure to the patient exceeds 30-40 cmH₂O. The valve opens to reduce the risk of stomach distention and barotrauma. A hissing sound can be heard when the valve opens. This safety valve may be overridden if more pressure to the patient is needed. To override: Press downwards on the pressure release valve.*

 *Note: For ventilation training with the NeoNatalie Newborn Simulator, use the largest mask (no.1). For ventilation of a real patient, use the mask size that provides the best seal to the patient's face.*

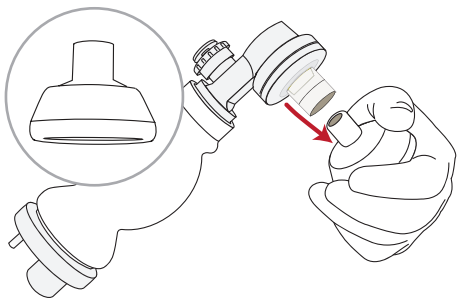
 *Note: If the Patient Valve becomes contaminated with vomitus shake free any contaminant and squeeze the silicone bag to deliver several sharp breaths through the Patient Valve to expel the contaminant. - If contaminant does not clear; disassemble the Patient Valve and rinse.*

 *Note: If any components are loose, tighten or reassemble the device and test in accordance with section 7.*

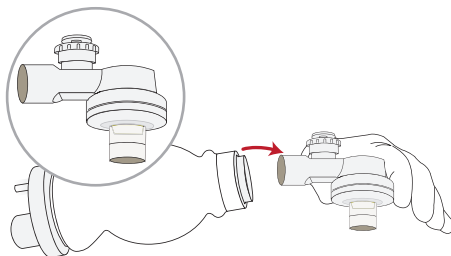
9 Dis-assembling the Resuscitator

Dis-assemble the resuscitator before performing the cleaning procedure. Also see Section 4 - Resuscitator Overview before dis-assembling the resuscitator.

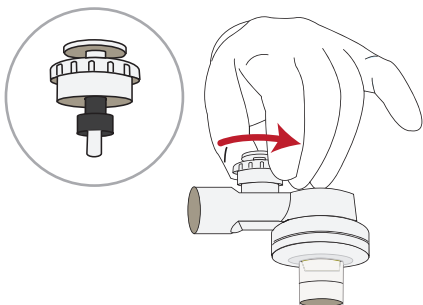
- 1 Pull the patient mask from the patient port connector.



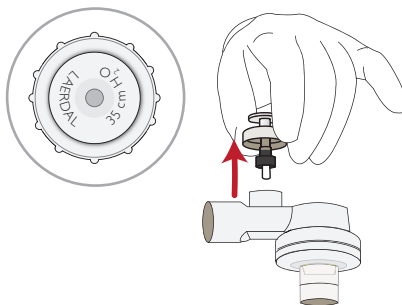
- 2 Pull the patient valve from the bag.



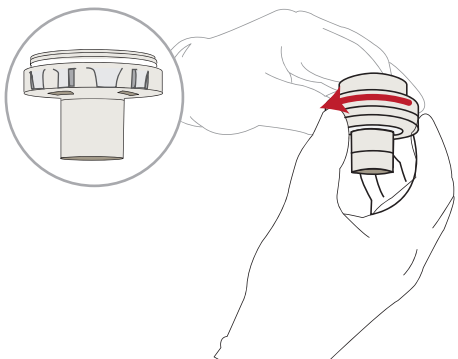
- 3 Unscrew the pressure release valve from the patient valve.



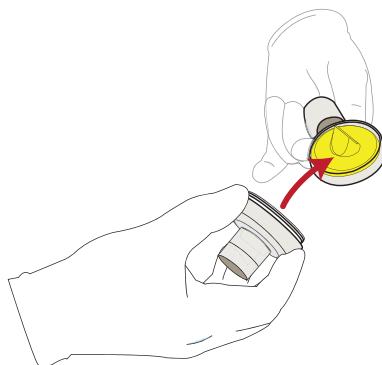
- 4 Remove the pressure release valve. Do not dis-assemble this part any further.



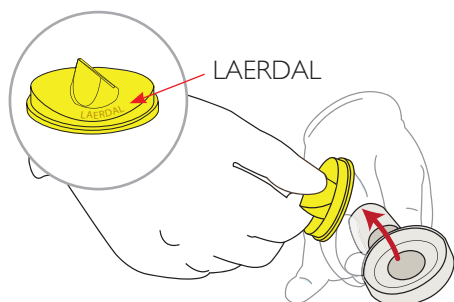
- 5 Unscrew the lower patient valve housing from the upper part.



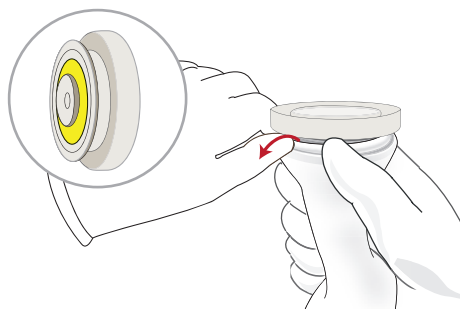
- 6 Remove the lower patient valve housing.



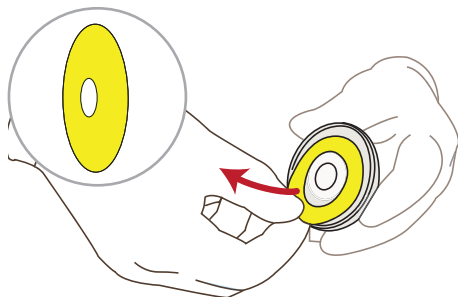
- 7 Remove the lip valve from the patient valve upper housing.



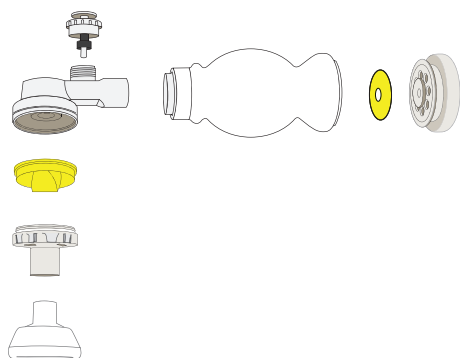
- 8 Squeeze the end of the bag and pull the bag over the inner rim of the inlet valve until the bag is free from the valve.



- 9 Pull the inlet valve disk membrane free from the ring in the inlet valve housing.



The resuscitator can now be cleaned and disinfected according to the procedure in Section 10.



10 Cleaning and Disinfection

1. Cleaning

- 1 Wash all parts in warm water using a mild detergent. Use a scrub brush / bottle brush to remove any soil.
- 2 Rinse the parts carefully with clean water to remove all soil and detergent.
- 3 Repeat the above steps. Inspect to ensure that no soil is visible. If necessary, the manual washing may be repeated.
- 4 Allow the parts to dry completely.
- 5 Continue with one of the disinfection methods below.

2. Disinfection

All resuscitator parts can be disinfected by one of the following approved methods, listed in descending order of efficiency.

Steam autoclaving

All resuscitator parts can be autoclaved in distilled water at 136 °C and 2.0 kg/cm for 10 - 20 minutes.

Chemical disinfection

All parts can be disinfected in an activated glutaraldehyde or Cidex solution of the recommended concentration.

Do as follows:

- 1 Rinse in clean water by totally immersing all parts.
- 2 Leave immersed in the solution for 60 minutes at 25 °C.
- 3 Remove parts from the solution using normal aseptic technique.
- 4 Rinse by immersing parts completely in 500 ml of clean water for 1 minute. Repeat once.

Boiling in water

Boil all resuscitator parts for approximately 10 minutes.

3. Drying

Dry all parts thoroughly before re-assembling.


11 Re-assembling the Resuscitator

To re-assemble the resuscitator, perform the steps described under Section 9 - Dis-assembling the Resuscitator, in reverse.

12 Storage

For clinical use, store according to local protocol. For training, keep in the supplied resuscitator's storage pouch.

13 Glossary of symbols

 0434 This product is in compliance with the essential requirements of Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC.

 This product does not contain latex.

14 Technical Information

Product meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators- Particular requirements for operator-powered resuscitators

Operating Temperature: - 18 °C to 50 °C

Storage Temperature: - 40 °C to 60 °C

Tidal volume: 161 ml* +/- 15 ml (standard deviation) at room temperature

* In sub-zero temperatures, the tidal volume may be approx. 20% less.

Expiratory Resistance: <2.5 cm H₂O at 5 LPM

Inspiratory Resistance: <0.5 cm H₂O at 5 LPM

Dead Space: 4 ml (water volume)

Materials

Hard plastic components: Polysulfone (PSU)

Soft plastic components: Silicone rubber (SI)

Spring: Stainless Steel

External dimensions (with mask): Approx. 220 mm x 70 mm x 120 mm

Mass (with mask size 1): Approx 170 grams

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

Made in China
NeoNatalie Resuscitator; Newborn - Reusable,
the Laerdal Logo, and "helping save lives" are all trademarks
of Laerdal Medical. © 2012, Laerdal Medical AS, All rights reserved.



Laerdal
helping save lives