

Reprocessing instructions

1. Product Overview

To disassemble, follow steps 1-7. To reassemble, follow the steps in reverse.

4

Unscrew

Pressure Release Valve

3

Take Out

Lip Valve Membrane

2

Unscrew

Patient Valve lower part

Patient Port Connector

1

Pull Off

Mask No. 1

5

Pull Out

Self-inflating Ventilation Bag

6

Pull Out

Inlet Valve Disk Membrane


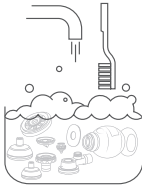

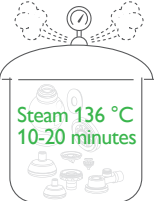
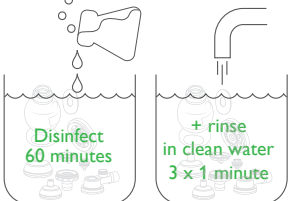


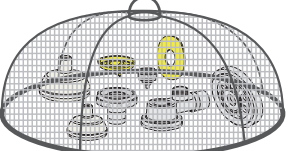
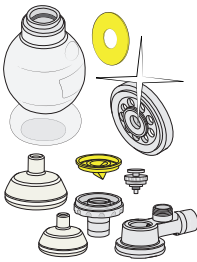
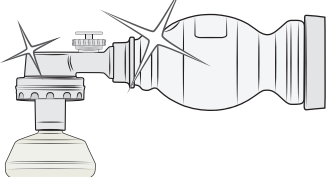
7

Pull Off

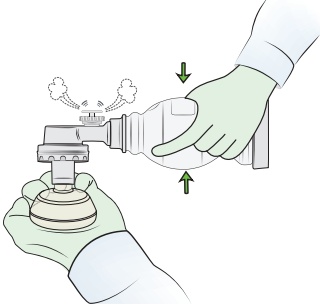
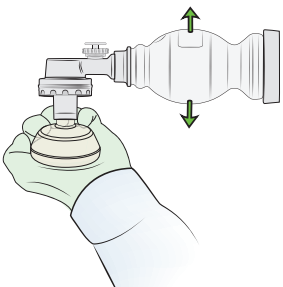
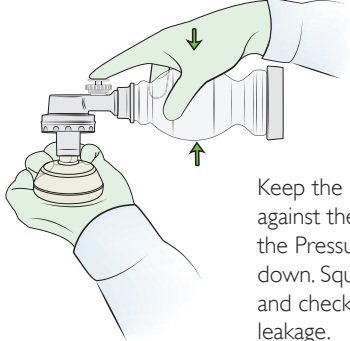
Inlet Valve Housing

Caution: Do not disassemble parts beyond the steps shown.

2. Cleaning and Disinfection Procedure

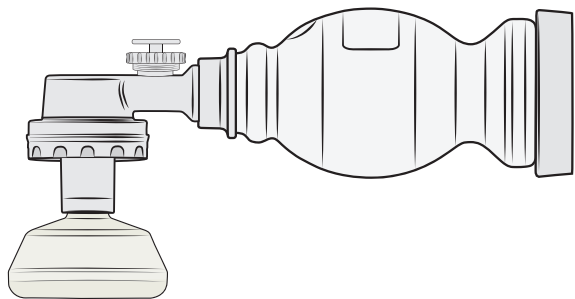
| Pre-disinfection | | | | |
|---|--|---|--|--|
| 1. Immediate Pre-Cleaning Wipe and clean the outside of the resuscitator with a piece of clean gauze soaked in 0.5 % chlorine solution. | 2. Disassembly  Always dismantle before cleaning. | 3. Manual Cleaning  Wash all parts in a clean tray with clean water and mild soap. Use a scrub or brush to remove any soil. | 4. Rinsing after cleaning Rinse parts thoroughly in clean water to remove all soil and soap. Repeat steps 3-4 until parts are clean. | 5. Post-Treatment  Before disinfection, dry with clean gauze or cloth. |
| Disinfection | | | | |
| 1. Choose one of the following disinfection methods: <div><div>Autoclaving  Steam 136 °C 10-20 minutes</div><div>OR</div><div>Chemical Activated glutaraldehyde 2.4%  Disinfect 60 minutes + rinse in clean water 3 x 1 minute Follow chemical manufacturer's instructions</div><div>OR</div><div>Boil or Steam*  Steam 100 °C 10-20 minutes *Validated at approximately sea-level pressure</div></div> | | | 2. Post-Treatment: <div><div>1. Remove parts using aseptic technique. </div><div>2. Allow parts to cool. Dry each part with sterile gauze or air dry in a protected space. </div></div> | |
| Post Disinfection | | | | |
| 1. Inspection Visually inspect each part for damage and cleanliness / mineral deposits. Remove damaged or unclean parts from service.  | Descaling If parts become coated in limescale immerse equal parts of water and white vinegar (3-5%) for 10 minutes. Rinse in clean water. Repeat if necessary. | 2. Reassembly Reassemble as shown above in 1. Product Overview.  | 3. Function Test See 3. Testing before Use below. | 4. Storage Store in a clean, enclosed space. |

3. Testing before Use

| 1. Lip Valve function | 2. Pressure Release Valve | 3. Inlet Valve opening | 4. Product sealing |
|---|---|---|--|
|  <p>Squeeze the bag. Check that the Lip Valve Membrane valve opens and closes with every squeeze.</p> |  <p>Seal the mask with a hand. Squeeze the bag forcefully. Check that air is released from the Pressure Release Valve.</p> |  <p>Keep the mask sealed against hand. Release the squeezed bag. Check that the bag re-expands without resistance.</p> |  <p>Keep the mask sealed against the hand. Press the Pressure Release Valve down. Squeeze the bag and check that there is no leakage.</p> |

NeoNatalie Resuscitator

NEWBORN BAG-MASK
REUSABLE - AUTOCLAVABLE



REF Cat. no. 846040 QTY 1 each

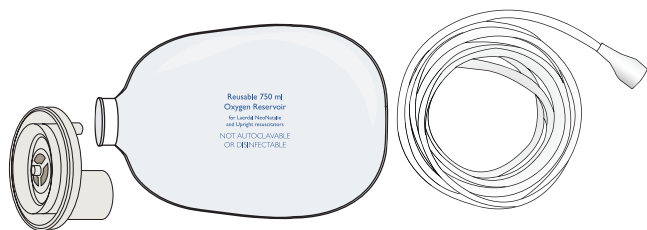


Laerdal
helping save lives

Accessories and Spare Parts

| Cat. no | Description |
|---------------|---|
| 846141 | Oxygen kit (NeoNatalie): Oxygen Reservoir Bag, Valve, Tubing and User Guide |
| 846130 | 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.



Oxygen kit
846141

User Guide

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.

Intended Use

The NeoNatalie Resuscitator is a self-inflating, manual resuscitator intended for newborns and infants up to 5 kg body mass who require respiratory support.

- 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).

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.*



Caution

Use only NeoNatalie Resuscitator parts from a Laerdal authorized source with this resuscitator.

Using the Resuscitator

- Pressure Release Valve:** The resuscitator has a pressure release (pop-off) valve which releases air when pressure to the patient exceeds 30-40 cmH₂O. A hissing sound can be heard when the valve opens. This valve may be overridden if more pressure to the patient is needed. To override: press downwards on the Pressure Release Valve with your index finger.
- 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.
- If the Patient Valve becomes contaminated with vomit, remove from patient and shake free any contaminant and squeeze the ventilation bag several times to expel the contaminant. If contaminant does not clear; disassemble the Patient Valve and rinse. If any components are loose, tighten or reassemble the device and test in accordance.

Important Product Information



2460

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

Technical Information

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 (-0.4 °F to 122 °F) |
| Storage temperature | - 40 °C to 60 °C (- 40 °F to 140 °F) |
| Dead space | 4 ml (water volume) |
| Tidal volume | 161 ml* +/- 15 ml (standard deviation) at room temperature |
| Expiratory resistance | <2.5 cm H ₂ O at 5 LPM |
| Inspiratory resistance | <0.5 cm H ₂ O at 5 LPM |
| Patient Connector (conical) | 15 mm inner diameter; 22 mm outer diameter |
| External dimensions (with Mask) | Approx. 220 mm x 70 mm x 120 mm (8.66 x 2.76 x 4.72 inches) |
| Mass (with Mask size 1) | Approximately 170 grams (6 ounces) |

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

Materials

Hard plastic components: Polysulfone (PSU)

Soft plastic components: Silicone rubber (SI)

Spring: Stainless steel



Not made with natural rubber latex

Global Warranty:

Refer to the Laerdal Global Warranty for terms and conditions. For more information visit www.laerdal.com

Manufactured in China for:

Laerdal Medical AS
P.O. Box 377, Tanke Svilandsgate 30
4002 Stavanger, Norway
Tel : +47 51 51 17 00
Fax: +47 51 52 35 57

NeoNatalie Resuscitator; Newborn - Reusable, the Laerdal Logo, and "helping save lives" are all trademarks of Laerdal Medical AS. Laerdal® is a trademark or registered trademark of Laerdal Medical AS.

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