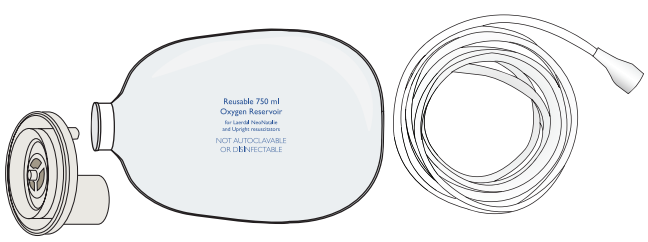
ACCESSORIES

Cat. no	Description
846141	Oxygen kit (NeoNatalie): Oxygen Reservoir Bag, Valve, Tubing and User Guide
850500	Expiration Diverter (OD 30 mm)

SPARE PARTS

Cat. no	Description
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*
540103	LSR Lip Valve

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



Oxygen kit
846141

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

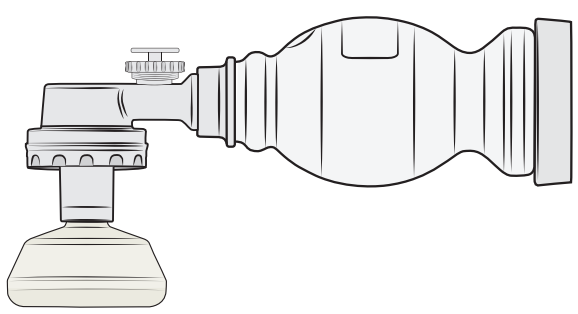
www.laerdal.com

20-19669 Rev A

EN

User Guide
NeoNatalie Resuscitator

NEWBORN BAG-MASK
REUSABLE - AUTOCLAVABLE



REF Cat. no. 846040 QTY 1 each

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SPECIFICATIONS

Conditions	
Operating Conditions	Temperature: -18 °C to 50 °C (-0.4 °F to 122 °F) Humidity: 15% to 95% RH
Storage Conditions	Temperature: -40 °C to 60 °C (-40 °F to 140 °F) Humidity: 15% to 95% RH
Inspiratory resistance	<0.5 cm H_2O at 5 LPM
Expiratory resistance	<2.5 cm H_2O 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)
Lifetime Parameters	
Shelf-life	5 years
Expected Service Life	50 cycles of reprocessing

Delivered volume range:
Tidal volume 161 ml* +/- 15 ml (standard deviation) at room temperature
* In sub-zero temperatures, the tidal volume may be approx. 20% less.

Material Chart	
Hard plastic components	Polysulfone (PSU)
Soft plastic components	Silicone rubber (SI)
Spring	Stainless steel

REGULATORY

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

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

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

CLINICAL INDICATIONS

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

Indication for Use
The NNR is intended for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen.

Intended Use
The NNR provides positive pressure ventilation and allows spontaneous breathing with a face mask or an artificial airway.
It is intended for newborns and infants up to 5 kg.

Intended Users
The NNR 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.

IMPORTANT INFORMATION

Read this User Guide and become familiar with the operation and maintenance of the product 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
Important information about the product or its operation.

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. Applied pressure should be adjusted and monitored according to the patient's condition.*
- *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.*
- *Care should be taken when using the NNR on patients with severely congested airways. Consider removing congestion from the oropharyngeal airway. Use of the NNR on patients with severely congested airways may result in a reduction in expected oxygenation.*
- *The NNR is not intended for use with advanced airways.*

Cautions
- *Use only NeoNatalie Resuscitator parts from a Laerdal authorized source with this resuscitator. Use of other parts may affect safety and/or performance.*
- *The resuscitator may be reused provided proper cleaning and sterilization procedures are performed between each patient use.*
- *The resuscitator components 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.*
- *The hard plastic components of the resuscitator are incompatible with polar solvents such as ethanol and isopropyl alcohol.*
- *The NNR and masks should only be used by persons who have received adequate training in the use of resuscitators.*
- *Resuscitators should not be used with supplemental oxygen where smoking is permitted or when fire, flame, oil or grease is in close proximity.*
- *Resuscitators should not be used in toxic or hazardous atmospheres.*
- *The use of third party products with the NNR may affect performance.*
- *Please consult with the manufacturer of the third party products to verify compatibility with the NNR and obtain information on possible performance changes.*
- *An oxygen blender is recommended if more precise oxygen concentrations are required, for example for pre-terms.*
- *The use of a PEEP valve (not provided by Laerdal) is recommended in the case that PEEP is indicated for the patient. Note that it is necessary to use the Expiration diverter to attach a PEEP valve.*
- *The NNR and masks are not intended for use in delivery of medications, such as anaesthetic gases.*

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.*

CLINICAL USE

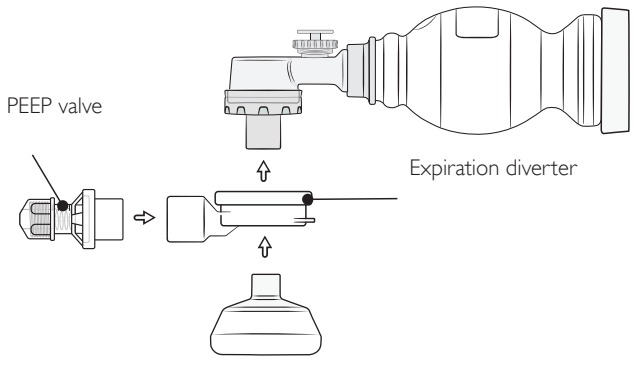
To Use
1. Connect a suitable face mask.
2. Connect to external O_2 source, if applicable.
3. Place mask over face and check for seal.
4. Squeeze the Ventilation Bag in accordance to clinical protocol.
5. Observe patient chest rise during ventilation.
6. Allow patient to exhale.
7. Stop ventilation as required by clinical protocol.

Pressure Release Valve:
The resuscitator has a pressure release (pop-off) valve which releases air when pressure to the patient exceeds 30-40 cm H_2O. 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.

The resuscitator may be fitted with the Laerdal LSR Expiration Diverter. Attach firmly to the Patient Port. Attach a suited PEEP valve if PEEP is indicated for the patient.
Check PEEP levels regularly with a manometer.



NeoNatalie Resuscitator

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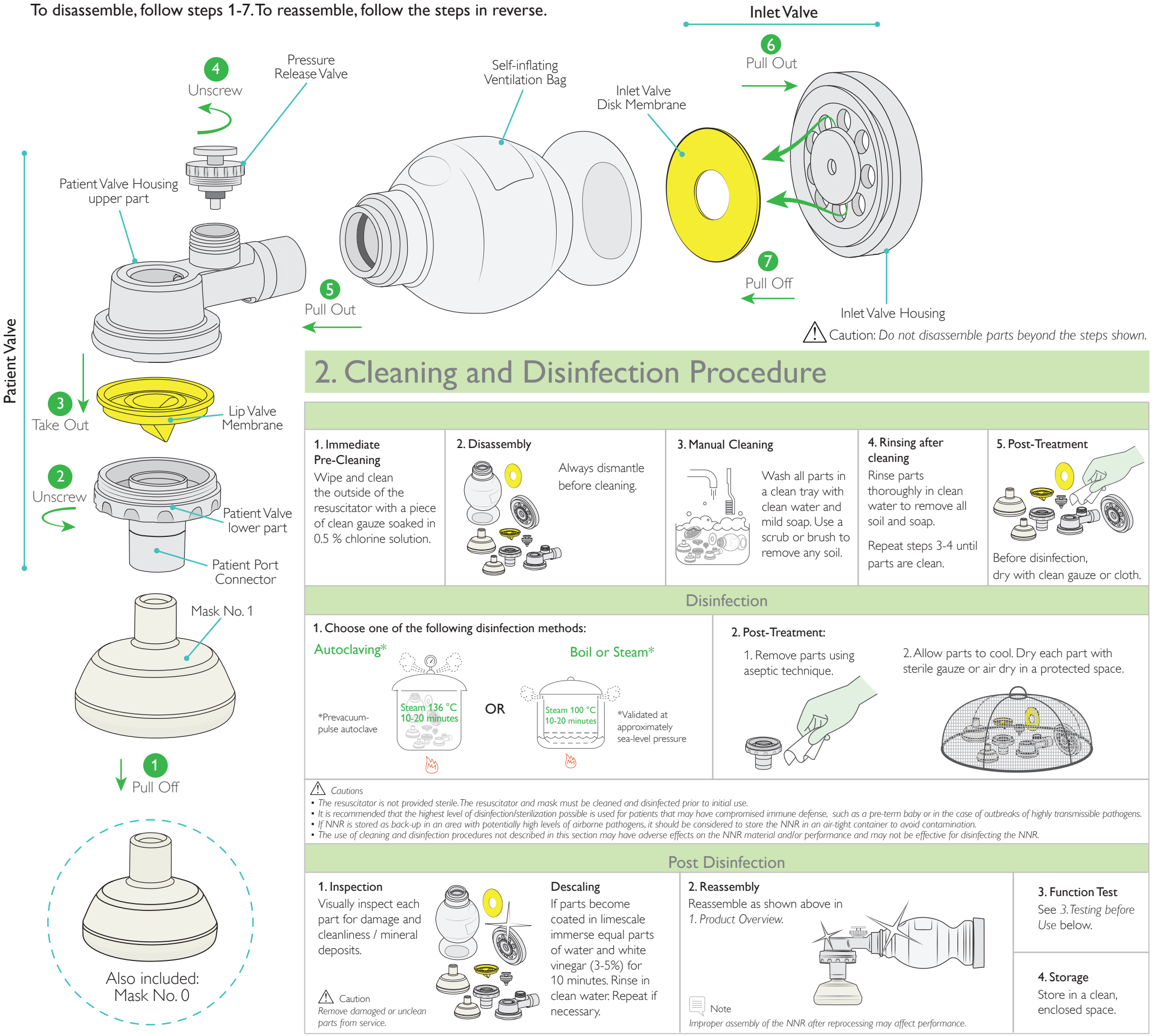
Reprocessing instructions

1. Product Overview

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



⚠ Caution: *Do not disassemble parts beyond the steps shown.*

2. Cleaning and Disinfection Procedure

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:

Autoclaving*

*Prevacuum-pulse autoclave

OR

Boil or Steam*

*Validated at approximately sea-level pressure

2. Post-Treatment:

1. Remove parts using aseptic technique.

2. Allow parts to cool. Dry each part with sterile gauze or air dry in a protected space.

⚠ *Cautions*
- *The resuscitator is not provided sterile. The resuscitator and mask must be cleaned and disinfected prior to initial use.*
- *It is recommended that the highest level of disinfection/sterilization possible is used for patients that may have compromised immune defense, such as a pre-term baby or in the case of outbreaks of highly transmissible pathogens.*
- *If NNR is stored as back-up in an area with potentially high levels of airborne pathogens, it should be considered to store the NNR in an air-tight container to avoid contamination.*
- *The use of cleaning and disinfection procedures not described in this section may have adverse effects on the NNR material and/or performance and may not be effective for disinfecting the NNR.*

Post Disinfection

1. Inspection
Visually inspect each part for damage and cleanliness / mineral deposits.

⚠ Caution
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.*

Note
Improper assembly of the NNR after reprocessing may affect performance.

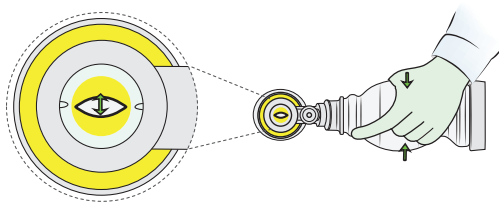
3. Function Test
See *3. Testing before Use* below.

4. Storage
Store in a clean, enclosed space.

3. Testing before Use

Inspect and test valve function to ensure proper operation of the NNR prior to patient use. To ensure proper operation, test valve functions after cleaning, disinfection and reassembly.

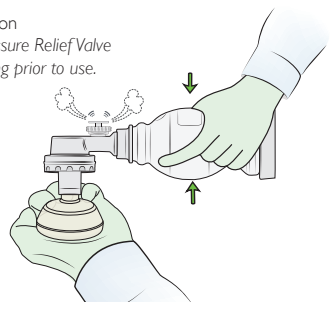
1. Lip Valve function



Squeeze the bag. Check that the Lip Valve Membrane valve opens and closes with every squeeze.

2. Pressure Release Valve

⚠ Caution
Ensure Pressure Relief Valve is functioning prior to use.

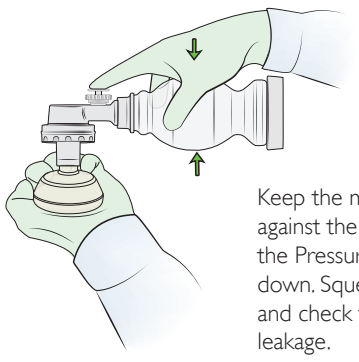


Seal the mask with a hand. Squeeze the bag forcefully. Check that air is released from the Pressure Release Valve.

3. Inlet Valve opening

Keep the mask sealed against hand. Release the squeezed bag. Check that the bag re-expands without resistance.

4. Product sealing



Keep the mask sealed against the hand. Press the Pressure Release Valve down. Squeeze the bag and check that there is no leakage.

- If any of the above tests fail, dismantle NeoNatalie Resuscitator, inspect the components, reassemble and repeat the complete procedure in 3. Testing Before Use.
- If NeoNatalie Resuscitator fails function tests it is to be removed from service and not used. Inspect all parts for damage. Replace any damaged parts if necessary and retest.