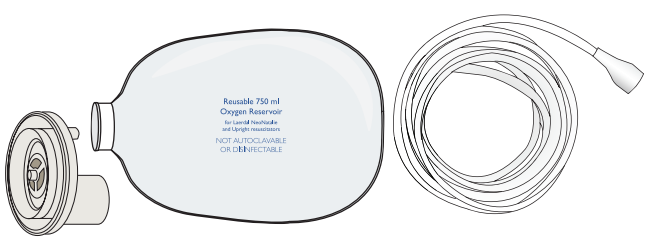
ACCESSORIES

Cat. no	Description
84614101	Oxygen Reservoir Accessory complete (NeoNatalie): Oxygen Reservoir Bag, Valve, Tubing and User Guide

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 Reservoir Accessory
84614101

Manufactured in China for:
Laerdal Medical AS
P.O. Box 377, Tanke Svilandsgate 30
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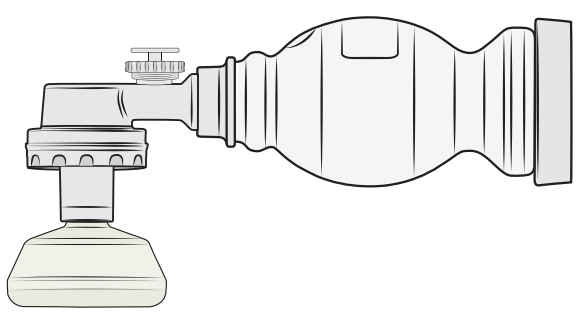
www.laerdalglobalhealth.com

20-08633 Rev C

EN

User Guide
NeoNatalie Resuscitator

NEWBORN - REUSABLE



REF Cat. no. 84604001 QTY 1 each

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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.*

⚠ Cautions
- *Use only NeoNatalie Resuscitator parts from a Laerdal authorized source with this resuscitator.*
- *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 Reservoir Accessory. The NeoNatalie Resuscitator is not supplied with the Oxygen Reservoir Accessory and its User Guide (sold separately).*
- *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 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.*
- This resuscitator is not intended for total use per patient of more than 24 hours.

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
Dead space	4 ml (water volume)
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
LATEX	Not made with natural rubber latex
℞ ONLY	Caution: Federal law (US) restricts this device to sale by or on the order of a physician.

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

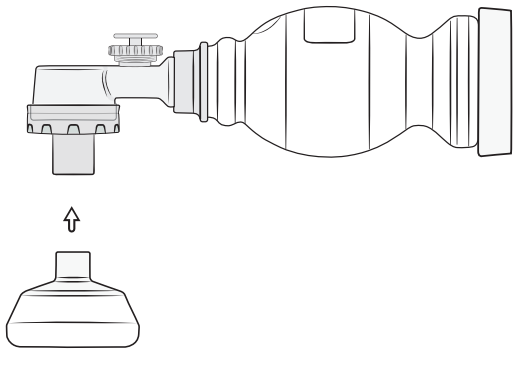
CLINICAL USE

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.



NeoNatalie Resuscitator

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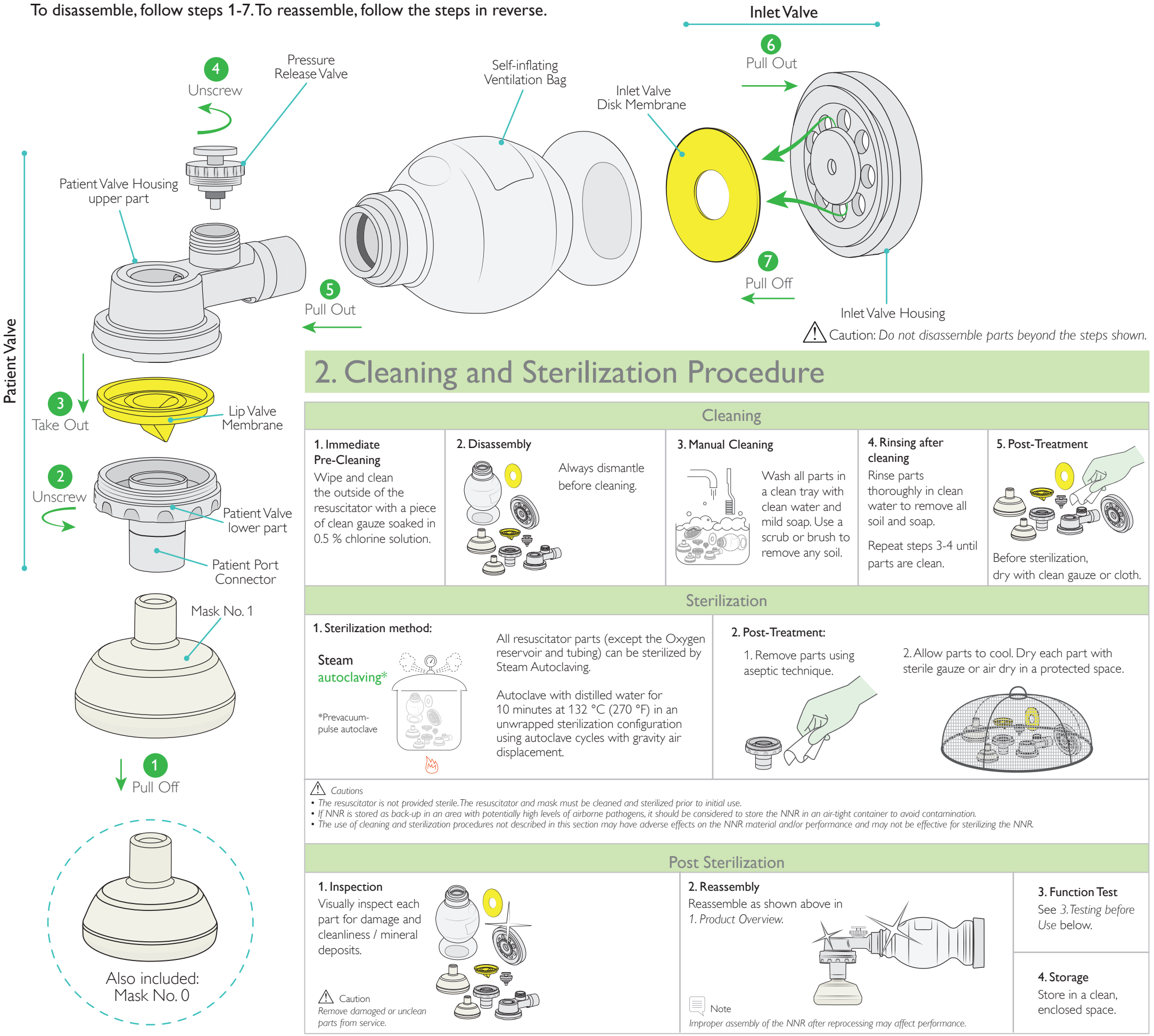
Reprocessing instructions

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 Sterilization Procedure

Cleaning

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 sterilization, dry with clean gauze or cloth.

Sterilization

1. Sterilization method:

Steam autoclaving*

*Prevacuum-pulse autoclave

All resuscitator parts (except the Oxygen reservoir and tubing) can be sterilized by Steam Autoclaving.

Autoclave with distilled water for 10 minutes at 132 °C (270 °F) in an unwrapped sterilization configuration using autoclave cycles with gravity air displacement.

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 sterilized prior to initial use.*
- *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 sterilization procedures not described in this section may have adverse effects on the NNR material and/or performance and may not be effective for sterilizing the NNR.*

Post Sterilization

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

⚠ Caution
Remove damaged or unclean parts from service.

2. Reassembly
Reassemble as shown above in *1. Product Overview.*

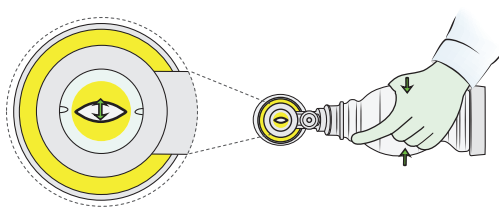
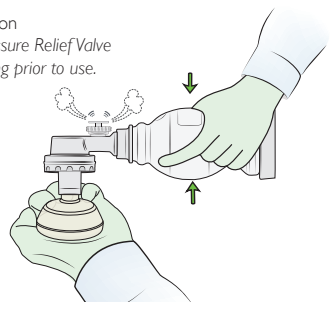
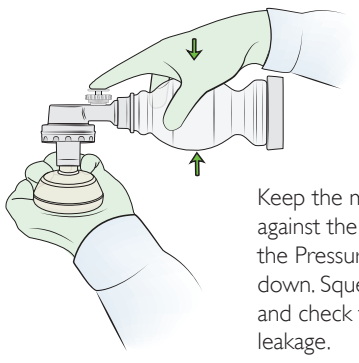
Note
Improper assembly of the NNR after reprocessing may affect performance.

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, sterilization and reassembly.

1. Lip Valve function	2. Pressure Release Valve	3. Inlet Valve opening	4. Product sealing
	⚠ Caution *Ensure Pressure Relief Valve is functioning prior to use.* 		
Squeeze the bag. Check that the Lip Valve Membrane valve opens and closes with every squeeze.	Seal the mask with a hand. Squeeze the bag forcefully. Check that air is released from the Pressure Release Valve.	Keep the mask sealed against hand. Release the squeezed bag. Check that the bag re-expands without resistance.	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.