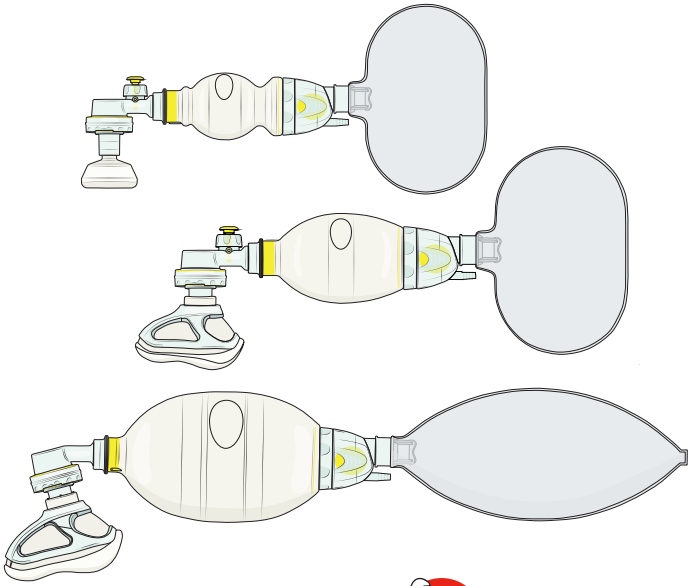
EN

Laerdal Silicone Resuscitators

User Guide



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helping save lives

Contents

Indication for Use

The Laerdal Silicone Resuscitator (LSR) is a self-inflating manual resuscitator that is intended for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen.

Intended Use

The Laerdal Silicone Resuscitator provides positive pressure ventilation and allows spontaneous breathing with a face mask or an artificial airway.

The Laerdal Silicone Resuscitator is available in three sizes:
The Adult model is intended for patients over 25 kg (55 lb).
The Paediatric model is intended for patients from 2.5 kg (5.5 lb) to 25 kg (55 lb).
The Preterm model is intended for patients below 2.5 kg (5.5 lb).

This User Guide applies to all three models of the Laerdal Silicone Resuscitator unless otherwise specified.

Important Information

Read this User Guide and become familiar with the operation of the product prior to use. Use the product only as described in this User Guide.

⚠ Warning 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 manikin.

Notes

Important information about the product or its operation.

⚠ Cautions

- *Caution: Federal law (US) restricts this device to sale by or on the order of a physician.*
- *The LSR 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 and oxygen delivery devices (e.g. filters and demand valves) with the Laerdal Silicone Resuscitator may have an affect on LSR performance. Please consult with the manufacturer of the third party device to verify compatability with the LSR and obtain information on possible LSR performance changes.*

Items Included

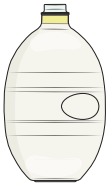
⚠ Caution

Do not use parts other than genuine Laerdal parts. Use of non-Laerdal parts may affect safety and/or performance.

Items may vary in appearance and are subject to change.

Adult Model
(Cat. No. 87xxxx)

Patient Valve



Adult Ventilation Bag
(1600 ml)

Reusable Oxygen
Reservoir Bag
(2600 ml)

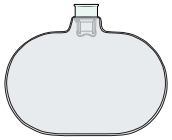
Silicone Mask
(Adult 4-5)
with Multi-Function
Mask Cover

Intake
Reservoir Valve

Paediatric Model
(Cat. No. 86xxxx)

Patient Valve with
Pressure Relief Valve

Paediatric Ventilation Bag
(500 ml)



Reusable Oxygen
Reservoir Bag
(600 ml)

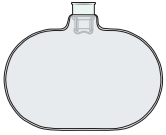
Silicone Mask
(Child 3-4)
with Multi-Function
Mask Cover

Intake
Reservoir Valve

Preterm Model
(Cat. No. 85xxxx)

Patient Valve with
Pressure Relief Valve

Preterm Ventilation Bag
(240 ml)

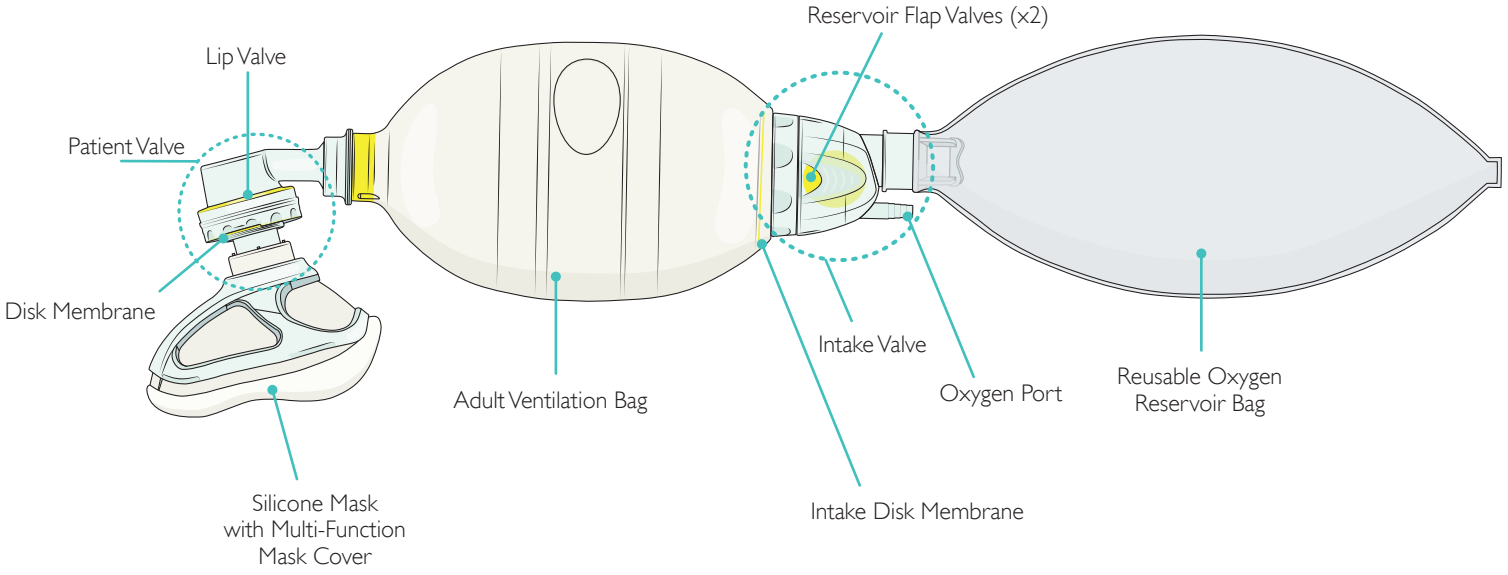


Reusable Oxygen
Reservoir Bag
(600 ml)

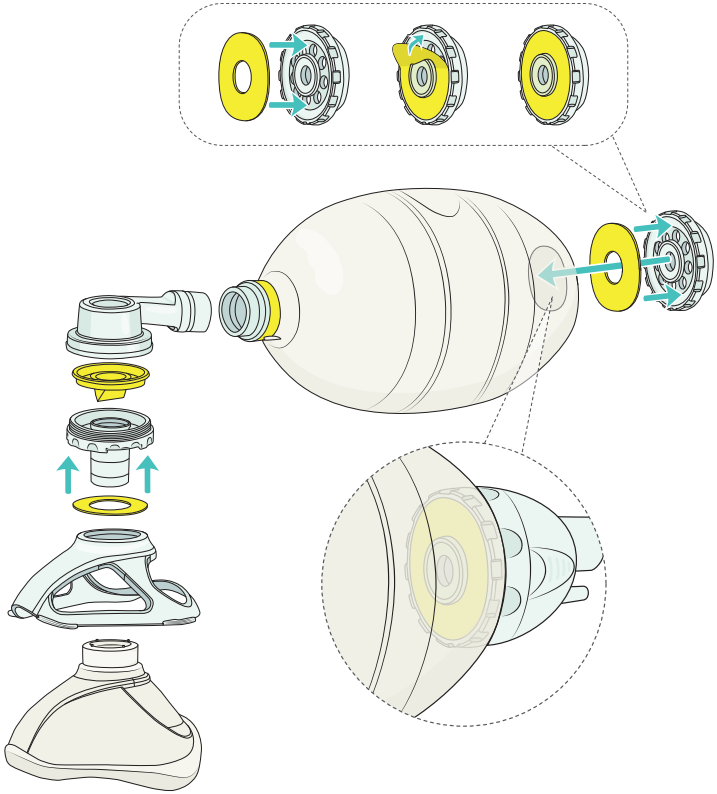
Silicone Mask
(Size 00, 0/1, 2)

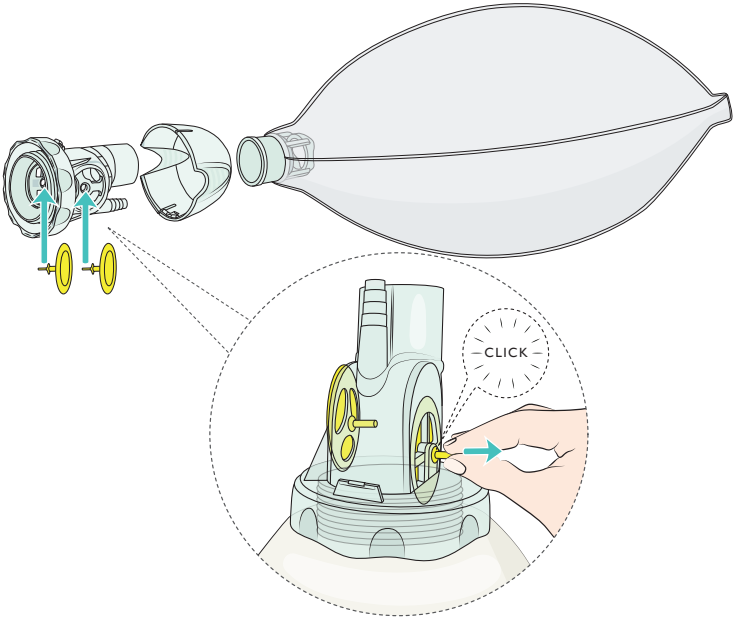
Intake
Reservoir Valve

Adult Model - Overview



Assembly and Disassembly

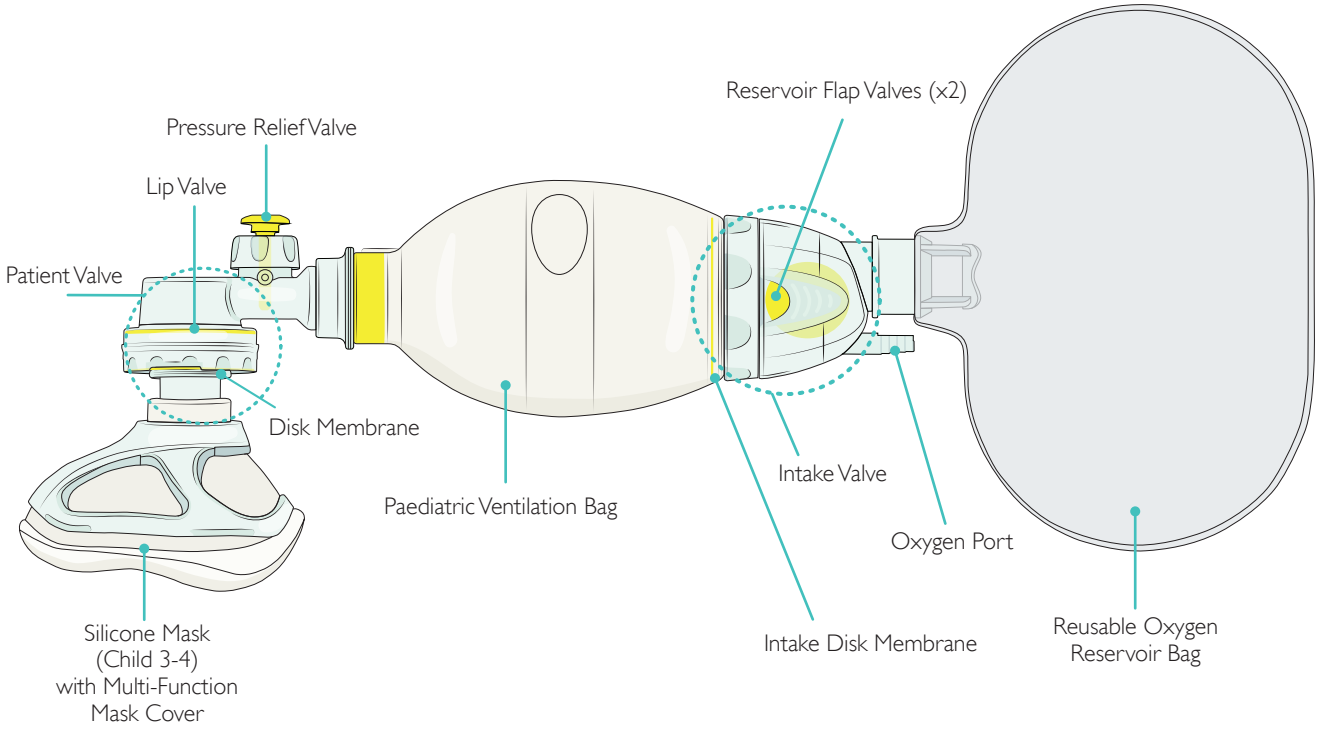




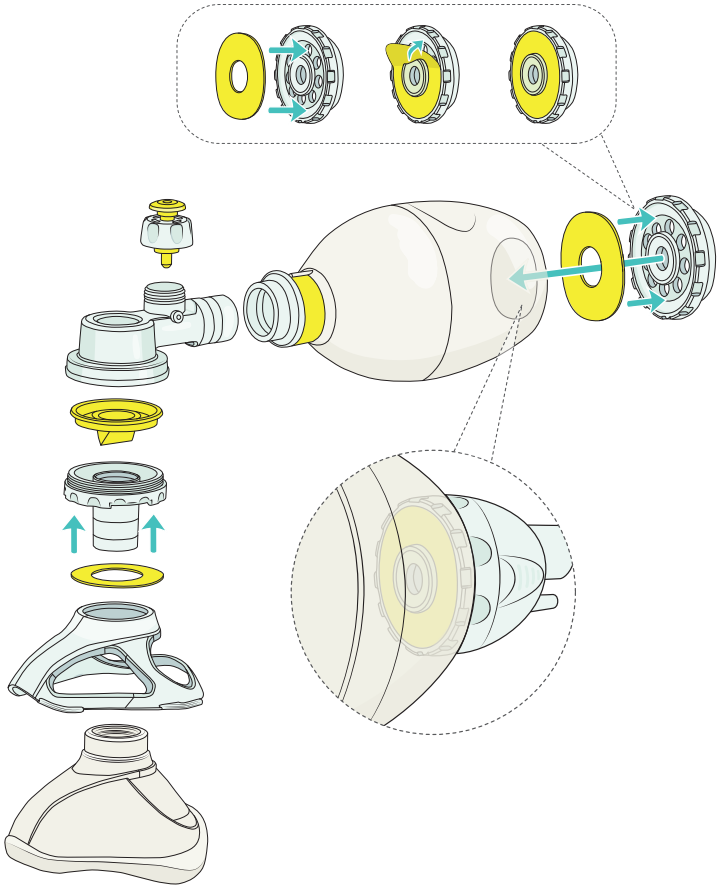
⚠ Cautions

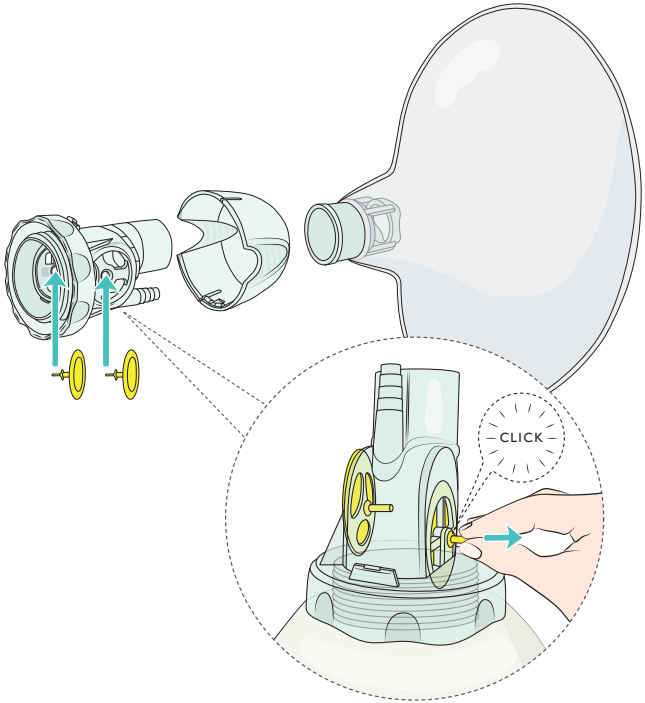
Improper assembly of the flap valves, intake membrane, disk membrane and lip valve may affect performance. Ensure use of one lip valve. Misassembly with two lip valves may cause inadvertent Positive End Expiratory Pressure (PEEP) or prevent proper patient exhalation.

Paediatric Model - Overview



Assembly and Disassembly

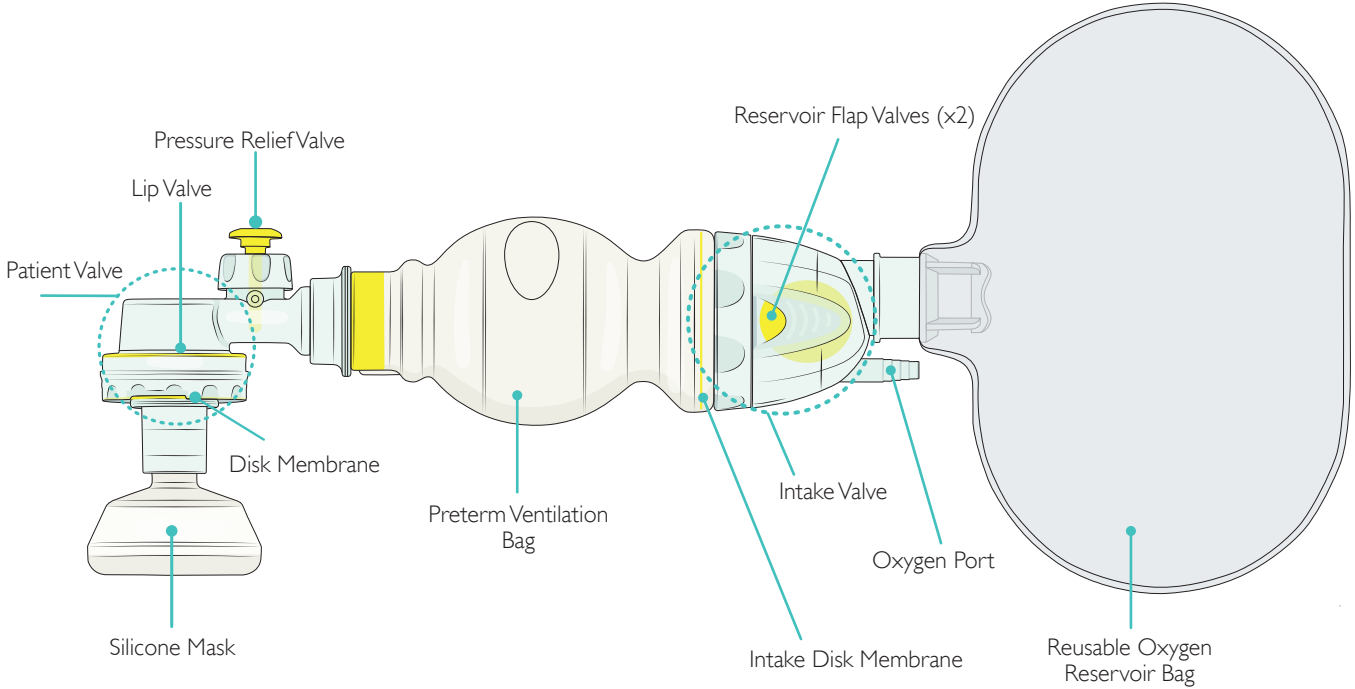




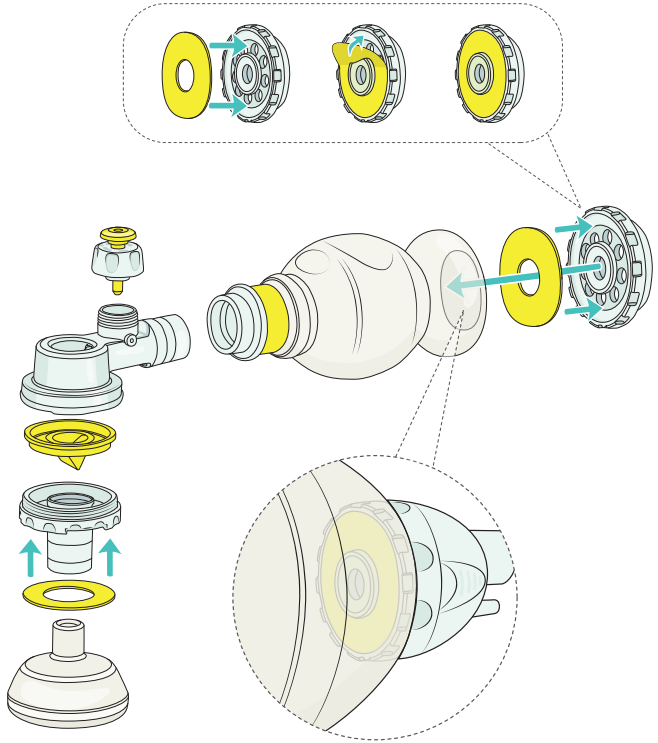
⚠ Caution

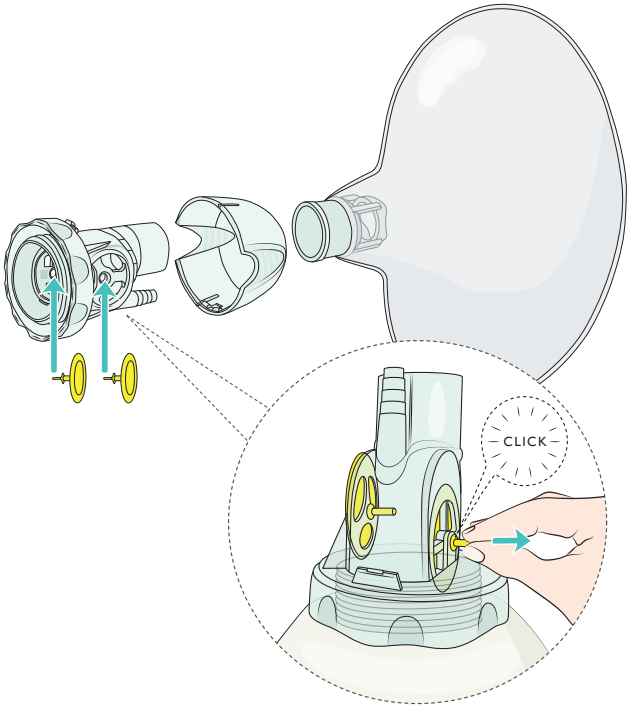
Improper assembly of the flap valves, intake membrane, disk membrane and lip valve may affect performance. Ensure use of one lip valve. Misassembly with two lip valves may cause inadvertent Positive End Expiratory Pressure (PEEP) or prevent proper patient exhalation.

Preterm Model - Overview



Assembly and Disassembly

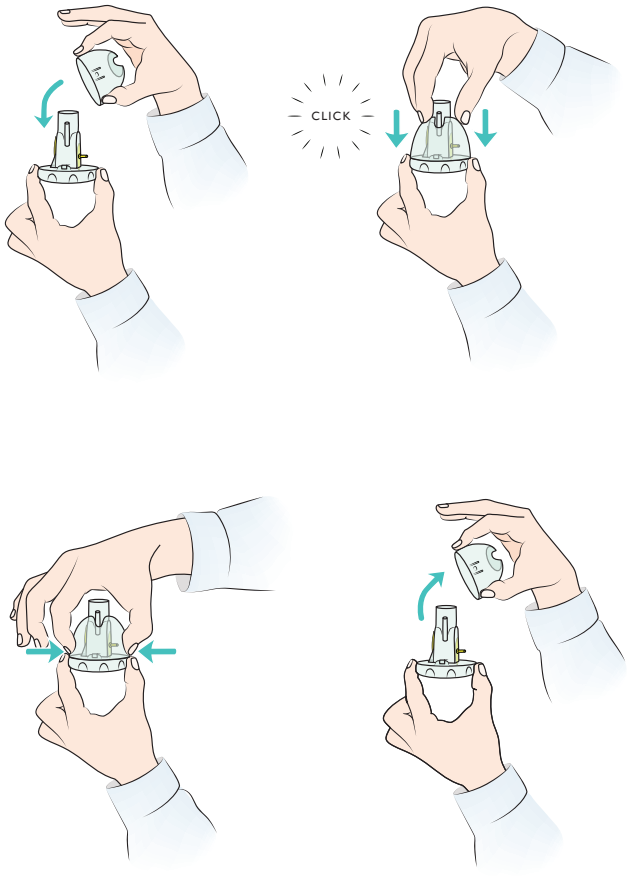




⚠ Caution

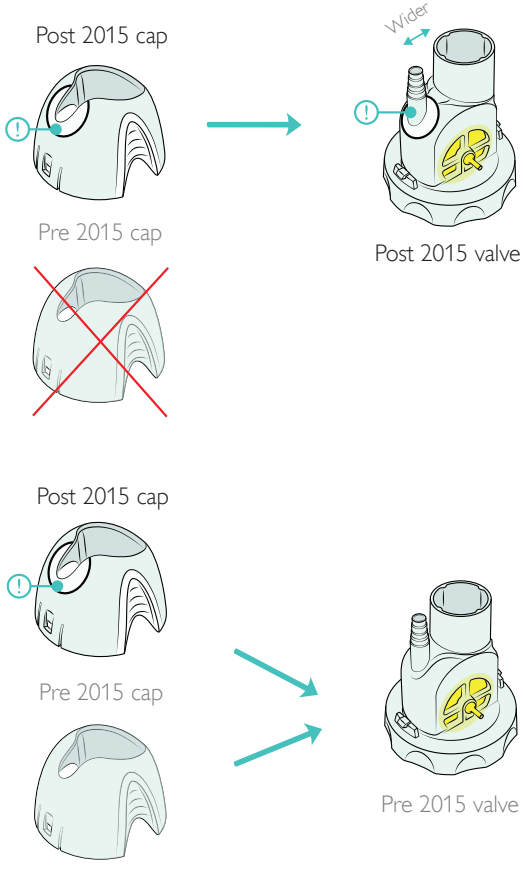
Improper assembly of the flap valves, intake membrane, disk membrane and lip valve may affect performance. Ensure use of one lip valve. Misassembly with two lip valves may cause inadvertent Positive End Expiratory Pressure (PEEP) or prevent proper patient exhalation.

Intake Valve Assembly/Disassembly



Intake Valve Cap Update

ⓘ New version of cap and valve are indentified by textured circle.



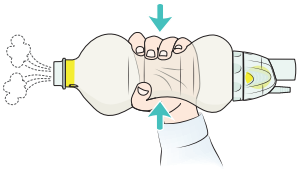
Inspect and test valve function to ensure proper operation of the Laerdal Silicone Resuscitator prior to patient use. To ensure proper operation, test valve functions after cleaning, disinfection and reassembly.

Laerdal Silicone Resuscitators should be function tested at least once every year.

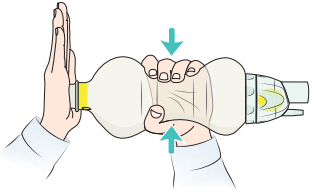
⚠ Caution

If a Laerdal Silicone Resuscitator fails any of these function tests it is to be correctly cleaned, re-assembled and tested or removed from service and not used.

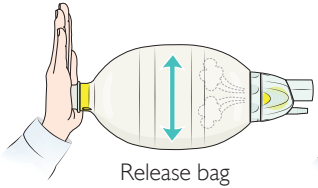
Testing the Intake Valve



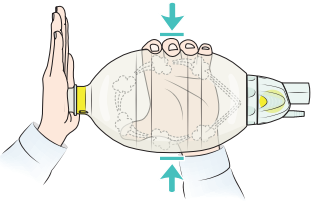
Squeeze



Seal neck



Release bag
Inspect Bag - must expand

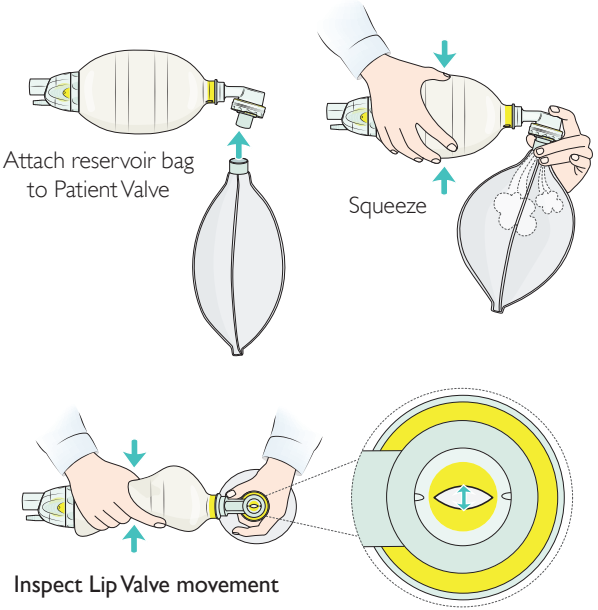


Try to squeeze
Inspect Bag - no air should escape

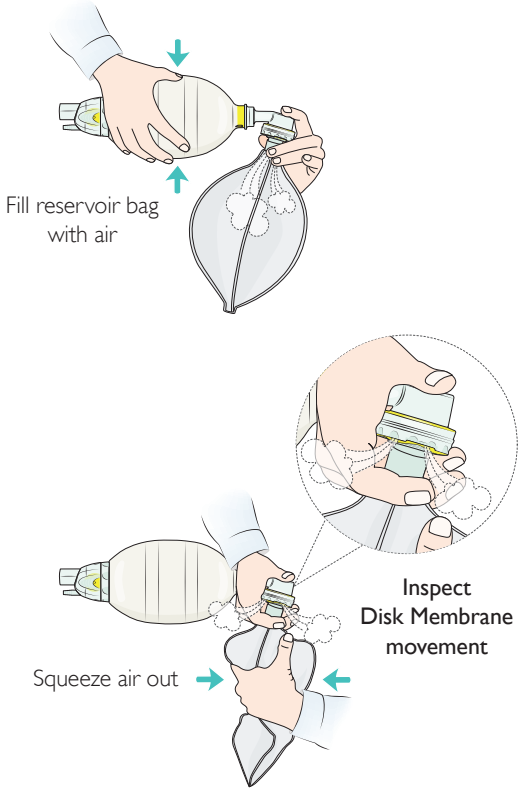
Testing the Patient Valve

⚠ Caution

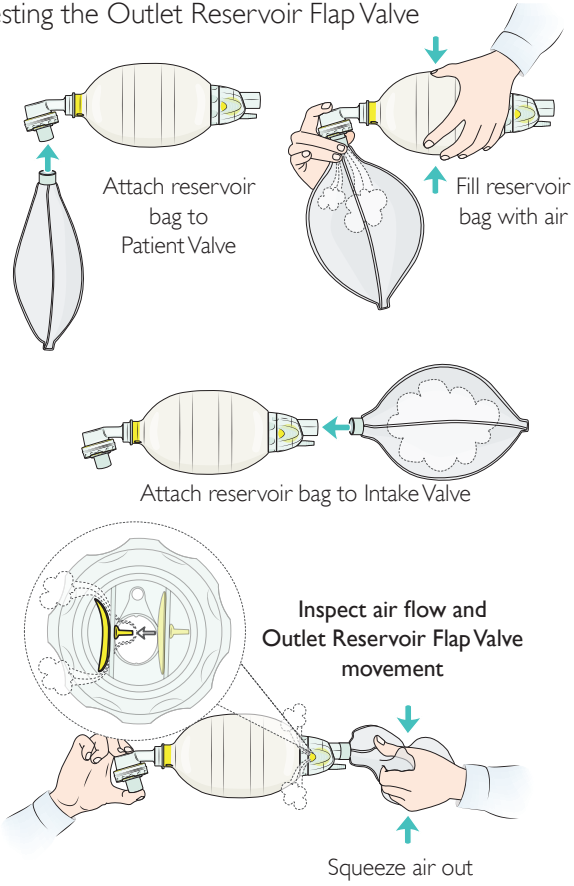
Ensure that a (single) Lip Valve has been installed in the Patient Valve.



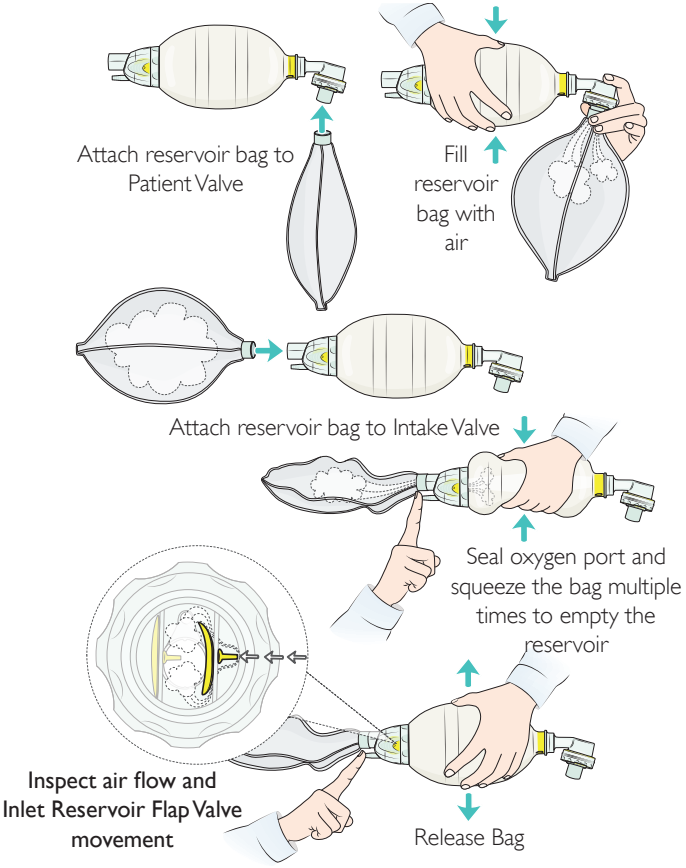
Testing the Disk Membrane of Patient Valve



Testing the Outlet Reservoir Flap Valve



Testing the Inlet Reservoir Flap Valve with Ambient Air

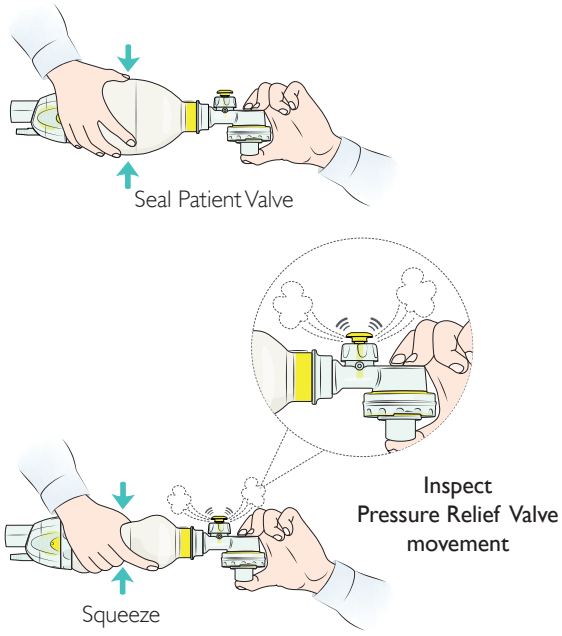


Testing the Pressure Relief Valve

Applies to Preterm and Paediatric models

⚠ Caution

Ensure Pressure Relief Valve is functioning prior to use.



⚠ Warning

Disposable Oxygen Reservoir Bag (870702)

Designed for single use only. Do not re-use. Re-use will lead to increased risk of cross contamination, degradation of performance and/or device malfunction. Laerdal is not responsible for any consequences of re-use.

⚠ Cautions

- *Laerdal strongly discourages the use of rinsing and drying agents. Such agents may not be compatible with the materials used in the Laerdal Silicone Resuscitator.*
- *The use of cleaning and disinfection procedures not described in this section may have adverse effects on the LSR material and/or performance.*
- *The LSR must be high-level disinfected before first time use.*
- *The resuscitator components must be cleaned and disinfected before next patient use.*

Note

Contamination: If the Patient Valve becomes contaminated with vomit during ventilation, disconnect the resuscitator from the patient and clear the Patient Valve as follows:

- *Tap the Patient Valve with the patient port against your gloved hand to 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.*

To reduce the risk of cross-contamination, follow these instructions after each use.

Inspection

Carefully inspect all parts for signs of wear or damage. Worn or damaged components must be discarded and replaced with new components.

Disassembly

Disassemble the LSR into individual parts as shown in Assembly and Disassembly section to make surfaces accessible to cleaning.

- Separate the Expiration Diverter (if used) into its three parts
- Separate the Patient Valve into its four main parts
- Separate the Intake Reservoir Valve into its six parts
- Leave connectors in the necks of the Ventilation Bag, Extension Tube and Reservoir Bag during the entire decontamination procedure.
- Unscrew the Pressure Relief Valve (Preterm and Paediatric models), but do not disassemble any further.

Washing and Rinsing

The LSR must be cleaned before high-level disinfection or sterilisation. The LSR can be manually cleaned, or cleaned in an automatic washer/disinfector.

Manual Cleaning
Rinse parts under cold running water.
Submerge parts in water at 30 - 40 °C (86 - 104 °F). Ensure that all surfaces are submerged for at least 2 minutes.
Submerge all parts in water at 60 - 70 °C (140 - 158 °F) which contains dish washing detergent.
Thoroughly clean all surfaces using a brush as necessary.
Rinse all components in detergent-free water at 30 - 40 °C (86 - 104 °F).
Dry the components thoroughly. Inspect all components to confirm that they are clean and dry. If parts are worn or damaged, discard them.
Automatic Cleaning *(applies to all parts except Reservoir Bags)*
Washer/Disinfector
Place parts in wire baskets.
Cycle 1: 90 - 95 °C (194 - 203 °F) for more than 12 seconds.
Total process time: approx. 52 min.
Cycle 2: Use a Non-enzymatic alkaline detergent containing 2 - 5% NaOH.
Pasteurmatic Compact
30 min wash cycle at 32 - 43 °C (90 - 110 °F)

Cleaning and Disinfection

To obtain high-level disinfection/sterilisation of the resuscitator, follow one of these methods.

Sterilisation/High-level Disinfection			
Method	**Process Parameters**		**Post-Treatment**
	Temperature / Concentration	**Exposure time**	
Sterilisation *(applies to all parts except the Reservoir Bags)*			
Steam Autoclaving (gravity-displacement)	Autoclave at 132 - 137 °C (270 - 279 °F)	15 min (+ 30s)	Allow parts to cool and dry
Steam Autoclaving (prevacuum-pulse)	Autoclave at 134 - 137 °C (273 - 279 °F)	3 min (+30s)	
High-level Disinfection *(applies to all parts)*			
Cidex OPA (orthophtalaldehyde)	0.55% solution	60 min	Remove traces of disinfectant by rinsing in warm tap water, 30 - 40 °C (86 - 104 °F), for at least 2 mins. Dry the components thoroughly.
Sodium Hypochlorite	0.5% solution	20 min	
Pasteurization	Pasteurization cycle 70 - 75 °C (158 - 167 °F)	30 min	Dry the components thoroughly

Reassembly

Reassemble resuscitator as shown in Assembly/Disassembly section.

Regulatory Information

CE 2460

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

Laerdal Silicone Resuscitator meets the following Standards:

- EN 1789
- ISO 10651-4
- ISO 13485
- ISO 14971
- ISO 5356-1
- ISO 10993-1

Recommendations:

- When used in accordance with ISO 10651-4 the following resuscitator size recommendation applies: Adult for patients over 20 kg (44 lb), Paediatric for patients from 2.5 kg (5.5 lb) to 20 kg (44 lb) and Preterm for patients below 2.5 kg (5.5 lb).
- When used to deliver tidal volumes as recommended by the AHA/ILCOR Guidelines 2010[1], the following applies. Adult for patients over 25 kg (55 lb), Paediatric for patients from 2.5 kg (5.5 lb) to 25 kg (55 lb) and Preterm for patients below 2.5 kg (5.5 lb).

[1] AHA/ERC AED Guidelines for CPR and Emergency Cardiovascular care (ECC) by ILCOR, AHA, ERC and others (2010).

Not made with natural rubber latex.

Adult Model

Ventilation Bag volume: 1600 ml
Reservoir Bag volume: 2600 ml

Delivered O_2 concentrations under various test conditions

O_2 flow (lpm)	Tidal volume (ml) x bag cycling rate per minute. O_2-concentrations (%) using reservoir (without reservoir)					
	400 x 12	400 x 24	600 x 12	600 x 24	1000 x 12	1000 x 24
3	74 (38)	51 (39)	58 (34)	40 (34)	44 (33)	33 (30)
8	100 (44)	100 (44)	100 (40)	68 (40)	78 (38)	51 (34)
15	100 (51)	100 (50)	100 (47)	100 (47)	100 (42)	75 (36)

Paediatric Model

Ventilation Bag volume: 500 ml
Reservoir Bag volume: 600 ml

Delivered O_2 concentrations under various test conditions

O_2 flow (lpm)	Tidal volume (ml) x bag cycling rate per minute. O_2-concentrations (%) using reservoir (without reservoir)					
	20 x 40	20 x 60	150 x 20	150 x 30	300 x 12	300 x 24
3	100 (97)	100 (97)	98 (56)	78 (57)	85 (48)	56 (46)
8	100 (100)	100 (100)	100 (70)	100 (70)	100 (58)	100 (57)
15	100 (100)	100 (100)	100 (82)	100 (83)	100 (71)	100 (70)

Preterm Model

Ventilation Bag volume: 240 ml
Reservoir Bag volume: 600 ml

Delivered O_2 concentrations under various test conditions

O_2 flow (lpm)	Tidal volume (ml) x bag cycling rate per minute. O_2-concentrations (%) using reservoir (without reservoir)					
	20 x 40	20 x 60				
3	100 (98)	100 (97)				
8	100 (100)	100 (100)				
15	100 (100)	100 (100)				

LSR Specifications

Conditions	
Operating Conditions	Temperature: -18 °C to 60 °C (0 °F to 140 °F) Humidity: 15% to 95% rH
Storage Conditions	Temperature: -40 °C to 70 °C (-40 °F to 158 °F) Humidity: 40% to 95% rH
Resistance	
Expiratory resistance	Approximately 2.6 cm H_2O Measured with airflow of 50 lpm
Inspiratory resistance	With Reservoir: approx. 4.2 cm H_2O Without Reservoir: approx. 3.1 cm H_2O Measured with airflow of 50 lpm

Specifications

Attainable delivery volume	
Adult	Approximately 800 ml
Paediatric	Approximately 320 ml
Preterm	Approximately 150 ml
Test conditions	Compliance 0.02 l/cm H_2O, Resistance 20 cm H_2O/l/s
No leakage	Pressure Relief Valve overridden
Dead space of Patient Valve	Approximately 7 ml for all models
Useful Life	
Laerdal Silicone Resuscitators should undergo the Function Test at least once every year. If a correctly assembled LSR fails the test, the failing parts must be replaced and disposed of.	

Spare Parts and Accessories

Accessories

Catalogue #	Description
871000	Silicone extension tube, 28 cm
850900	LSR Manometer connector
850500	Expiration diverter (OD 30 mm)
531907	LSR Intake Valve Outer Part (23 mm OD)
865200	Multi Function Mask Cover for Mask 3-4
875200	Multi-Function Mask Cover 4-5+
870400	LSR Head strap
870120	LSR Hanging loop
54010733	High Efficiency Filter for LSR/TheBAG(IE)(25pk)
572000	Wall mount, Adult Display Case

Spare Parts/Consumables

Catalogue #	Description
540103	LSR Lip valve
851252	Pressure Relief Valve 35 cm H20
851103	LSR Lock clips,(pkg-10)
540105	LSR Disk membranes, pkg. 10
511700	LSR Wall bracket
531904	LSR Reservoir valve lid
560200	LSR Patient Valve

871300	Attachment ring for head strap
850150	Preterm Bag, 240 ml
860150	Paediatric Bag, 500 ml
870150	Adult Bag, 1600 ml
860410	LSR Compact Case
875400	Intake Reservoir Valve
531901	LSR O_2 reservoir 2.6 litre
531906	LSR O_2 reservoir 2.6 liters x 50
551901	LSR O_2 reservoir 0.6 litre
510404	LSR Intake membranes pkg. 10
871950	Flap Valves 2 pk.
510103	Cap for LSR Intake Valve spare part pkg. 3
860420	LSR Compact Case Adult
870600	LSR Display case cpl. Adult
860300	Display Case, Paediatric
850700	Display Case, Preterm
530400	Airways, set of 4
871950	Flap Valves 2 pk.
870708	Disposable O_2-reservoir bag, 2600ml, pkg.20

851250	Patient Valve w/35cm H_2O Pressure Relief Valve
521100	Wall Mount Paediatric/ Preterm Display Case

Masks

Catalogue #	Description
851500	LSR Silicone mask No.00
851600	LSR Silicone mask No.0/1
851700	LSR Silicone mask No.2
860220	Child Silicone mask 3-4 w/Multi Function Mask Cover
870220	Adult Silicone mask 4-5+ w/Multi Function Mask Cover
860221	Child Silicone mask 3-4 w/o Multi Function Mask Cover
870221	Adult Silicone mask 4-5+ w/o Multi Function Mask Cover
872220	Adult & Child Sil. Mask w/Multi Func. Mask Covers

For latest version of Spare Parts and Accessories, visit www.laerdal.com.

Warranty

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

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Printed in China

20-10368 Rev C

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