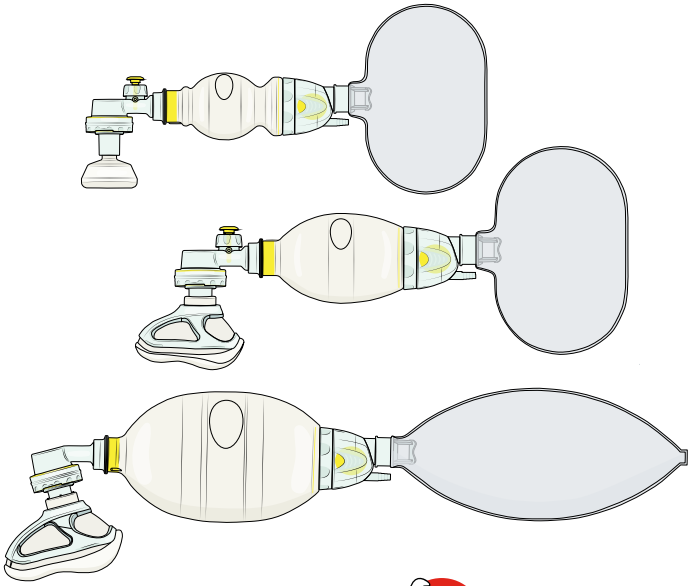
EN

Laerdal Silicone Resuscitators

User Guide



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Contents

Clinical Indications	4
Important Information	6
Items Included	8
Adult Model	10
Paediatric Model	16
Preterm Model	22
Intake Valve	28
Function Test	29
Clinical Use	36
Cleaning and Disinfection	38
Regulatory Information	42
Specifications	44
Spare Parts and Accessories	48

Device Description

The Laerdal Silicone Resuscitator (LSR) is a self-inflating manual resuscitator that is intended for patients requiring total or intermittent ventilatory support.

Indication for Use

The Laerdal Silicone Resuscitator (LSR) is intended for patients requiring total or intermittent ventilatory support. Ventilation is possible with or without supplemental oxygen.

Intended Use

The Laerdal Silicone Resuscitator (LSR) 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 (44 lb).
- The Paediatric model is intended for patients from 2.5 kg (5.5 lb) to 25 kg (44 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. For the Masks, refer to the Laerdal Silicone Mask User Guide.

Intended Users

The LSR 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 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 product damage.

Notes

Important information about the product or its operation.

Warnings

- *The LSR and masks should only be used by persons who have received adequate training in the use of resuscitators. Incorrect operation of the resuscitator can be hazardous.*
- *Care should be taken when using the LSR on patients with severe 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 using the LSR on patients with severe pulmonary disease or severely immature lungs. Applied pressure should be adjusted and monitored according to the patient's condition. Note that a manometer is not supplied by Laerdal for use with the LSR, but a manometer is possible to connect to the patient port with an appropriate adapter compatible with a ISO 5356-1 connector.*
- *Care should be taken when applying pressure to the mask to avoid facial damage, especially in the case of pediatric patients, infants,*

pre-terms, patients with severe osteoporosis and geriatric patients.
- *Care should be taken when using the LSR on patients with severely congested airways. Consider removing congestion from the oral cavity. Use of the LSR on patients with severely congested airways may result in a reduction in expected oxygenation.*
- *No pressurized gases or medications should be applied between the LSR and an artificial airway.*

Cautions

- *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 (such as filters and demand valves) with the Laerdal Silicone Resuscitator may affect performance. Please consult with the manufacturer of the third party products to verify compatability with the LSR and obtain information on possible performance changes.*
- *For a more accurate lower delivered oxygen concentration, use an oxygen blender/mixer set to the desired oxygen concentration.*
- *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 LSR and masks are not intended for use in delivery of medications, such as anaesthetic gases.*

Note

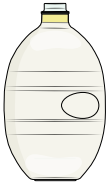
Should any serious malfunction, undesirable incident with, or deterioration in the functionality or performance of the device occur, contact Laerdal promptly. The competent authority where the incident took place and/or the device was used should also be notified.

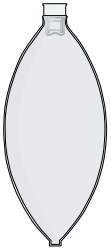
Items Included

⚠ Caution
Use of non-Laerdal parts may affect safety and/or performance.

Adult Model
(Cat. No. 87xxxx)


Patient Valve


Adult Ventilation Bag
(1600 ml)


Reusable Oxygen
Reservoir Bag
(2600 ml)


Silicone Mask
with Multi-Function
Mask Cover *

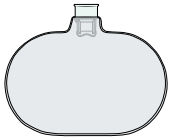

Intake
Reservoir Valve

* Depending on configuration.

Paediatric Model
(Cat. No. 86xxxx)


Patient Valve with
Pressure Relief Valve


Paediatric Ventilation Bag
(500 ml)


Reusable Oxygen
Reservoir Bag
(600 ml)

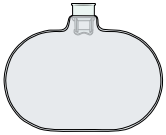

Silicone Mask *


Intake
Reservoir Valve

Preterm Model
(Cat. No. 85xxxx)


Patient Valve with
Pressure Relief Valve


Preterm Ventilation Bag
(240 ml)

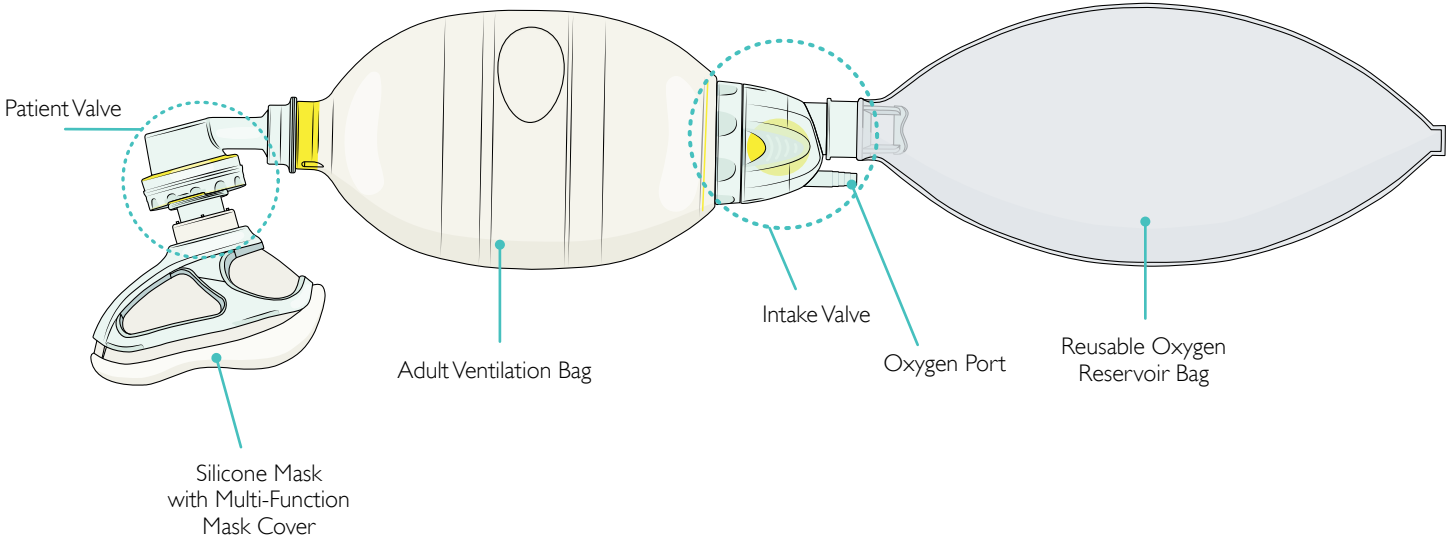

Reusable Oxygen
Reservoir Bag
(600 ml)


Silicone Mask *

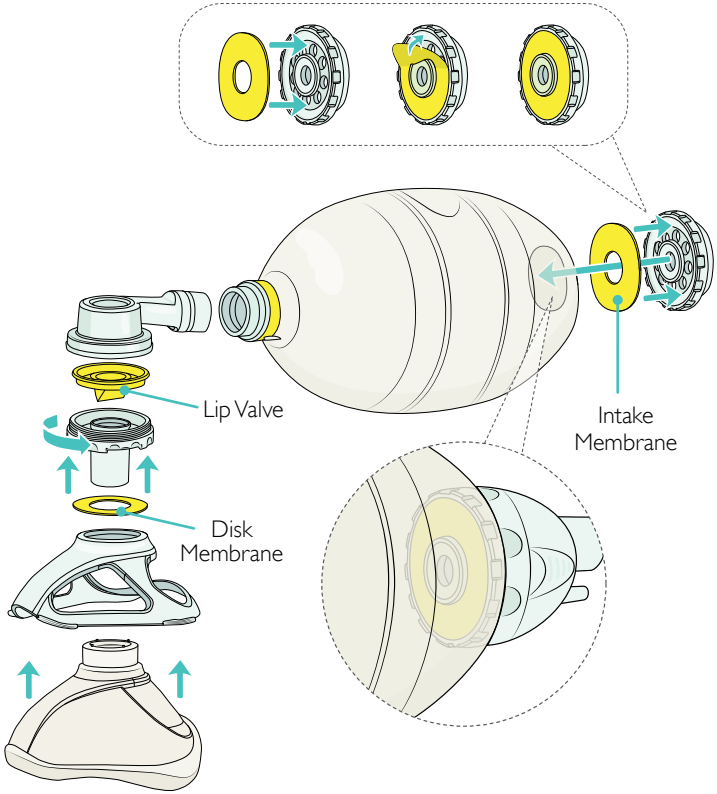

Intake
Reservoir Valve

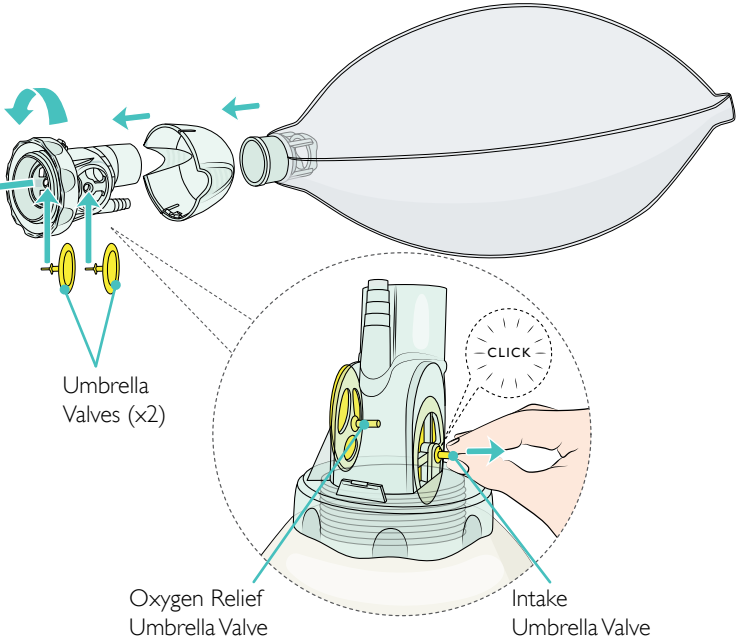
* Depending on configuration.

Adult Model - Overview



Assembly and Disassembly

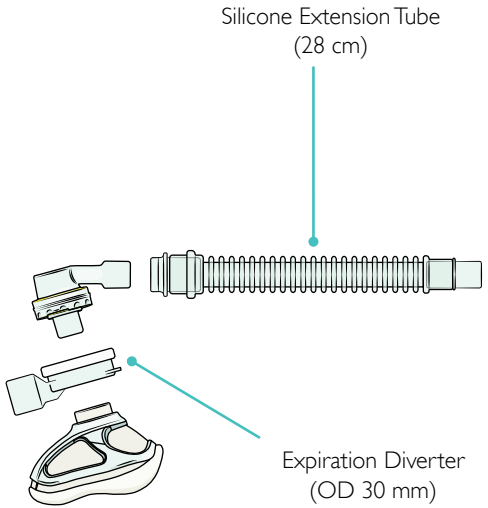




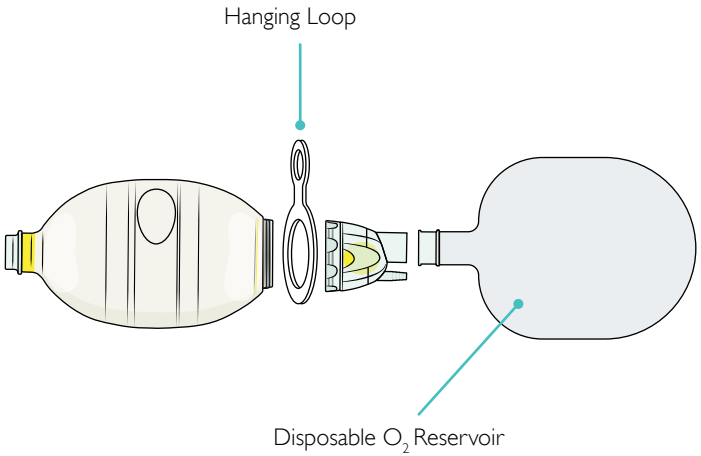
⚠ Warning

Improper assembly may affect performance. Ensure use of one lip valve. Misassembly with two lip valves may prevent proper patient exhalation.

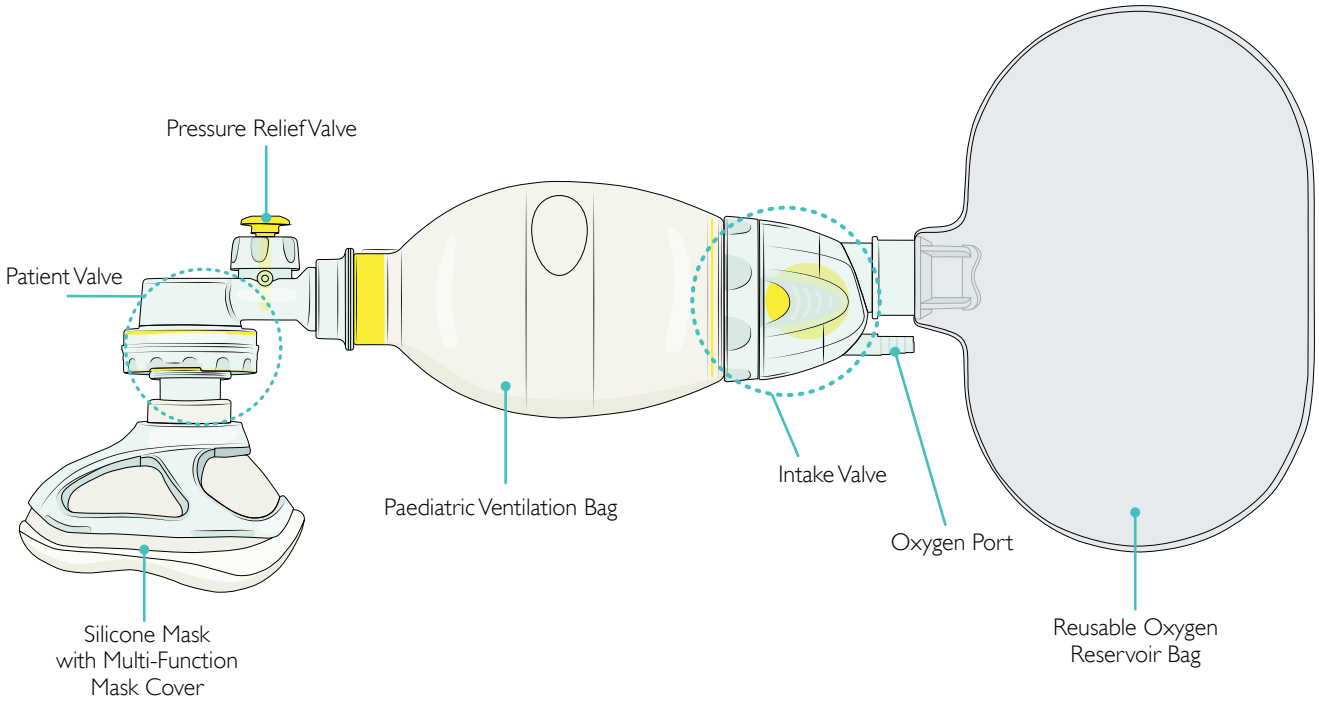
Accessories



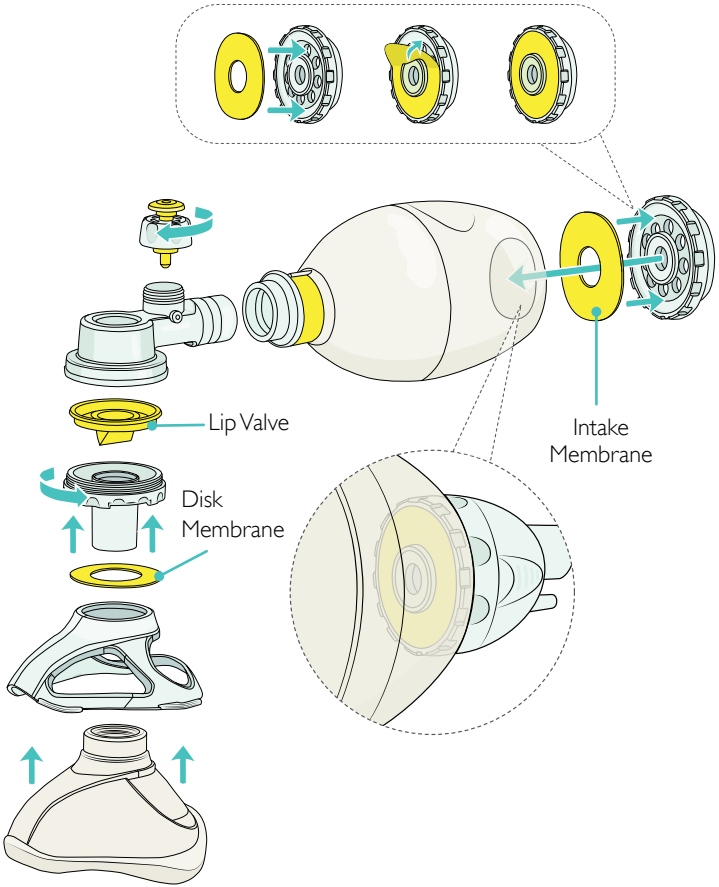
Adult Model - Overview



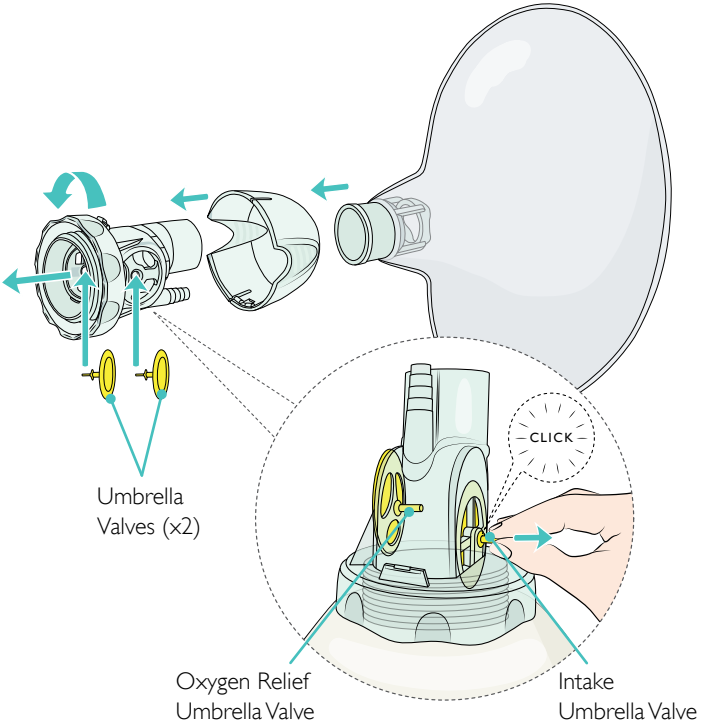
Paediatric Model - Overview



Assembly and Disassembly



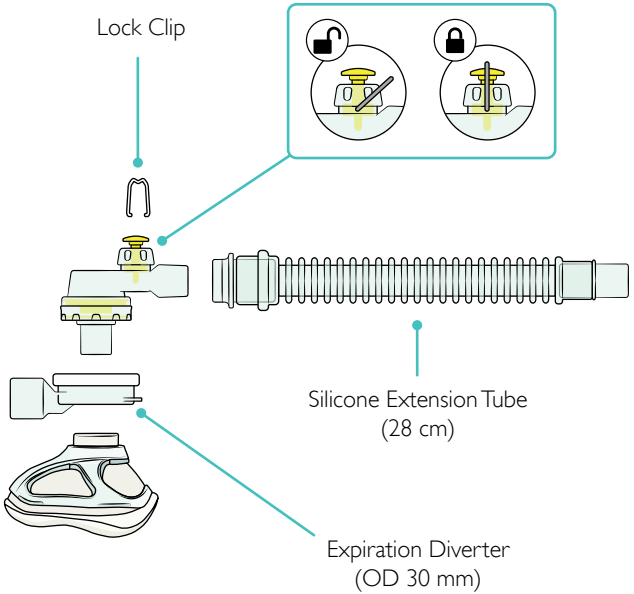
Paediatric Model - Overview



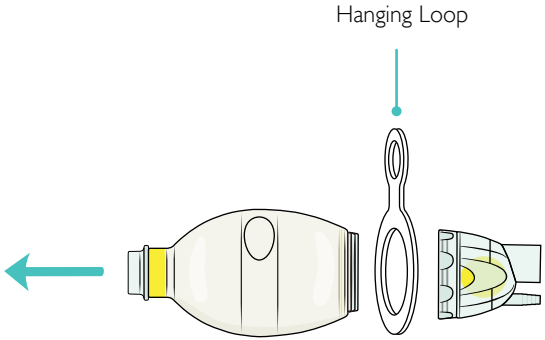
⚠ Warning

Improper assembly may affect performance. Ensure use of one lip valve. Misassembly with two lip valves may prevent proper patient exhalation.

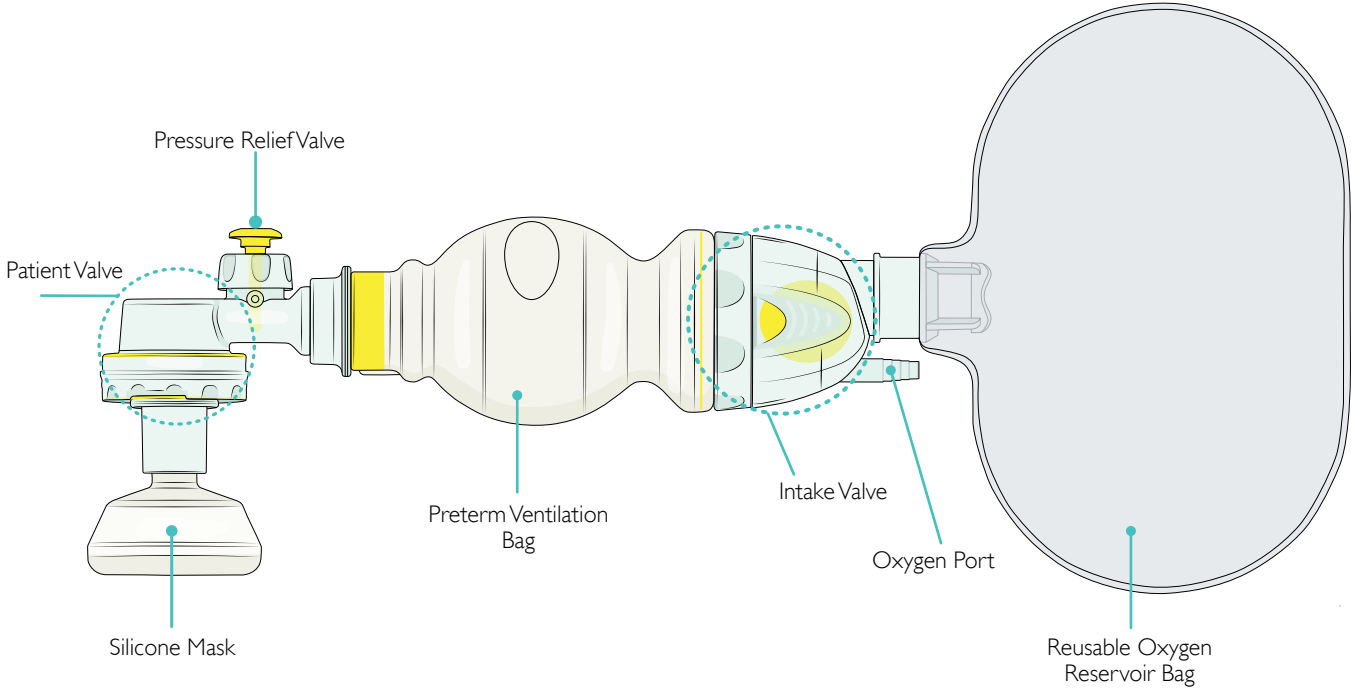
Accessories



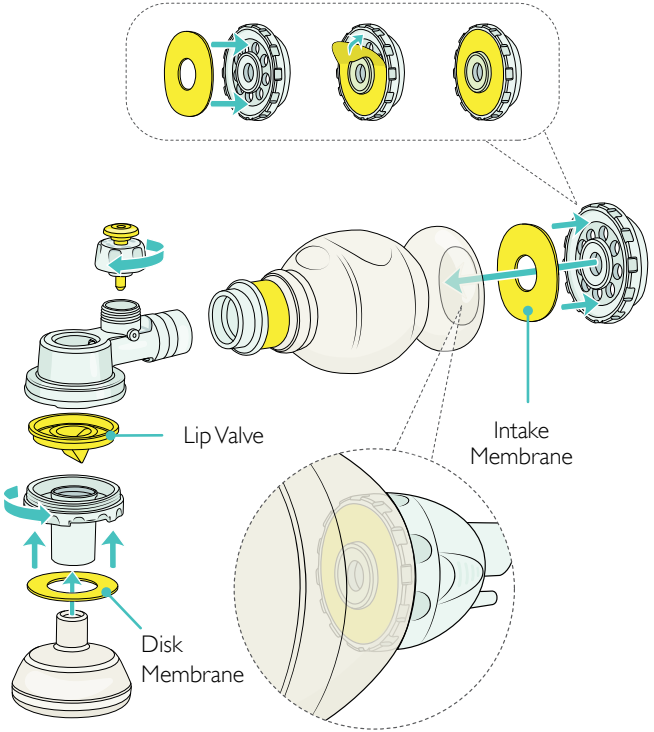
Paediatric Model - Overview

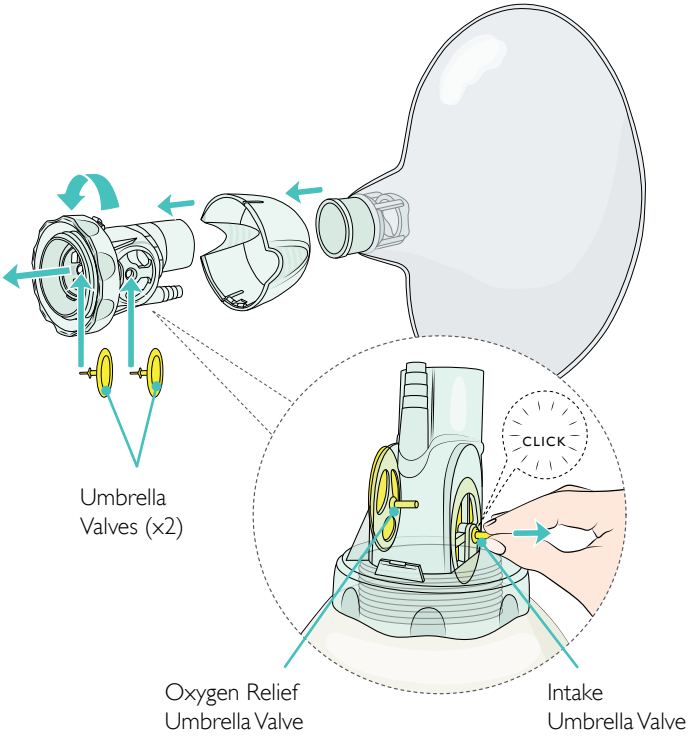


Preterm Model - Overview



Assembly and Disassembly

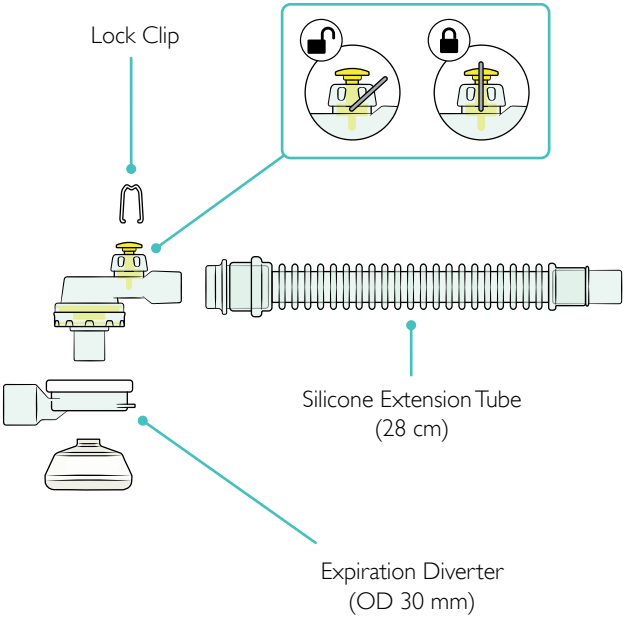


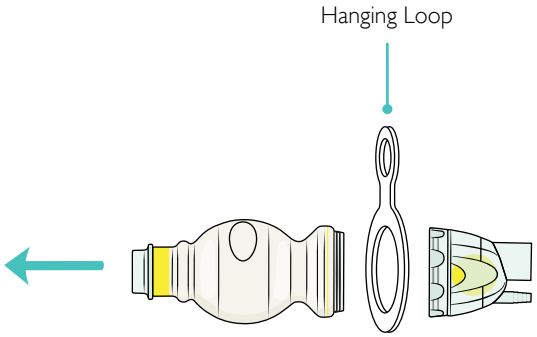


⚠ Warning

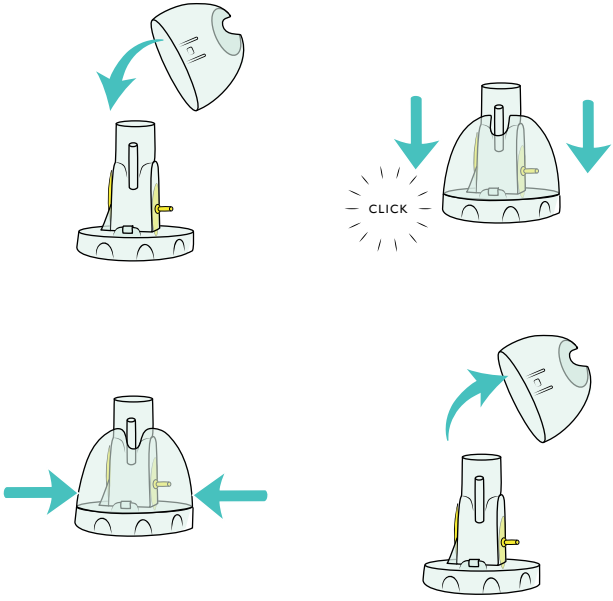
Improper assembly may affect performance. Ensure use of one lip valve. Misassembly with two lip valves may prevent proper patient exhalation.

Accessories





Intake Valve Assembly/Disassembly



Intake valve caps produced prior to 2015 are not compatible with LSRs produced after 2015.

Pre 2015 cap

Post 2015 cap

Function Test

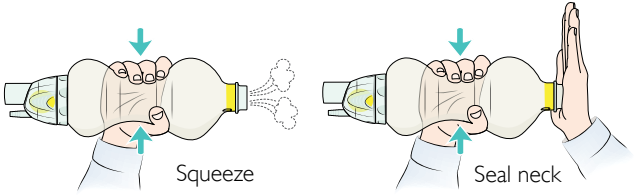
Inspect and test valve function to ensure proper operation of the Laerdal Silicone Resuscitator prior to patient use.

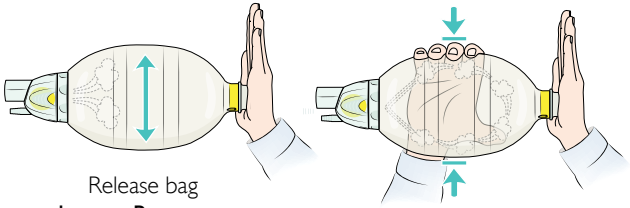
To ensure proper operation, test valve functions after cleaning, disinfection and reassembly.

⚠ Caution

If a Laerdal Silicone 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.

Testing the Intake Valve

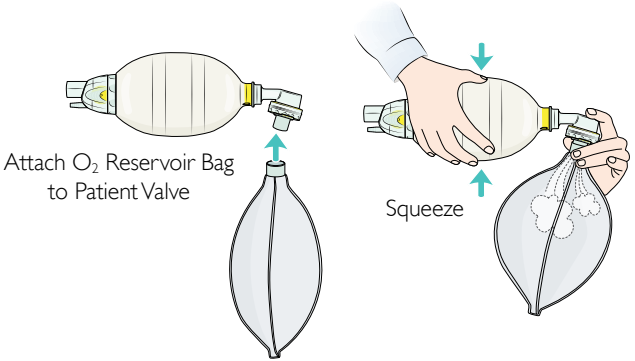


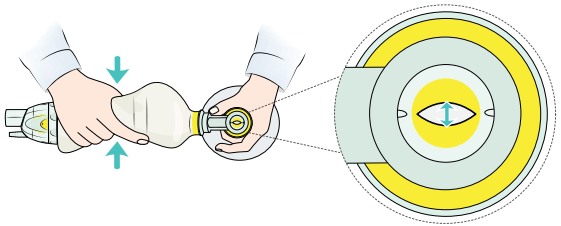


Release bag
Inspect Bag - must expand

Try to squeeze
Inspect Bag - no air should escape

Testing the Patient Valve

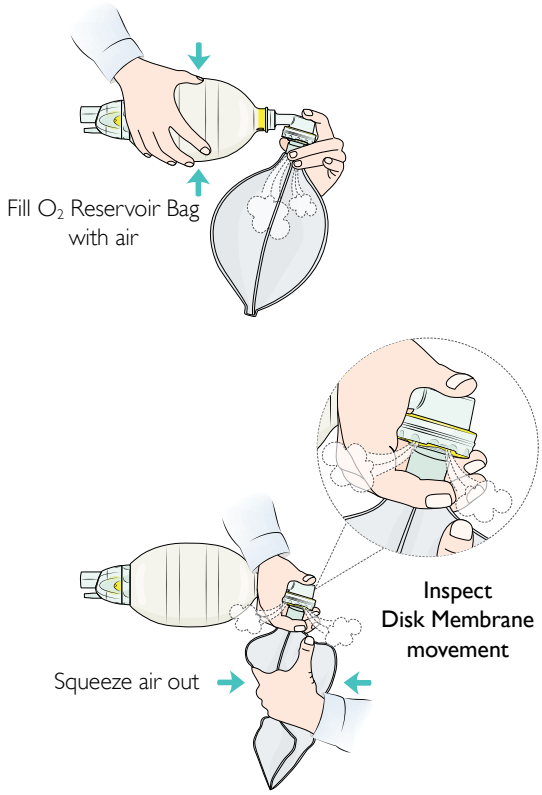




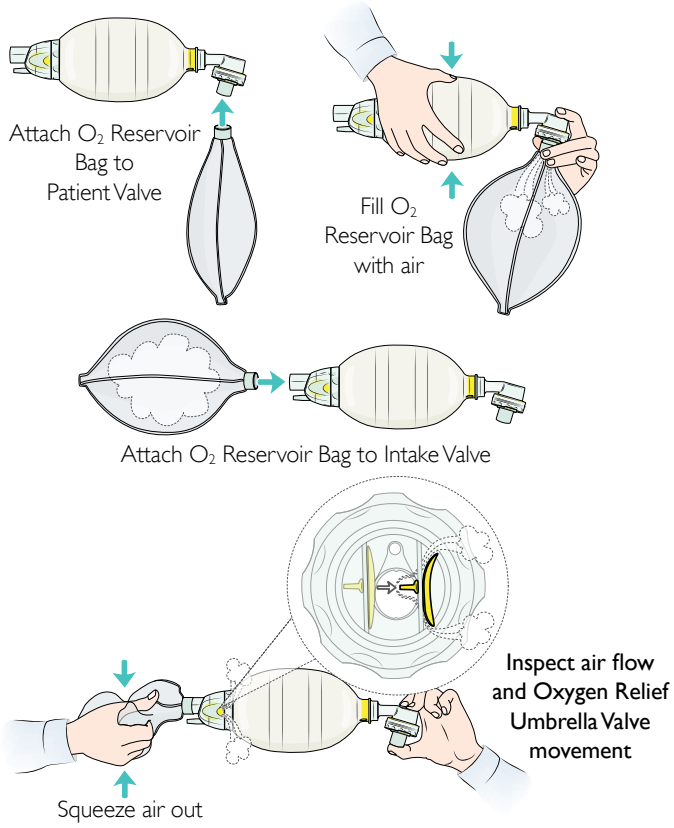
⚠ Warning

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

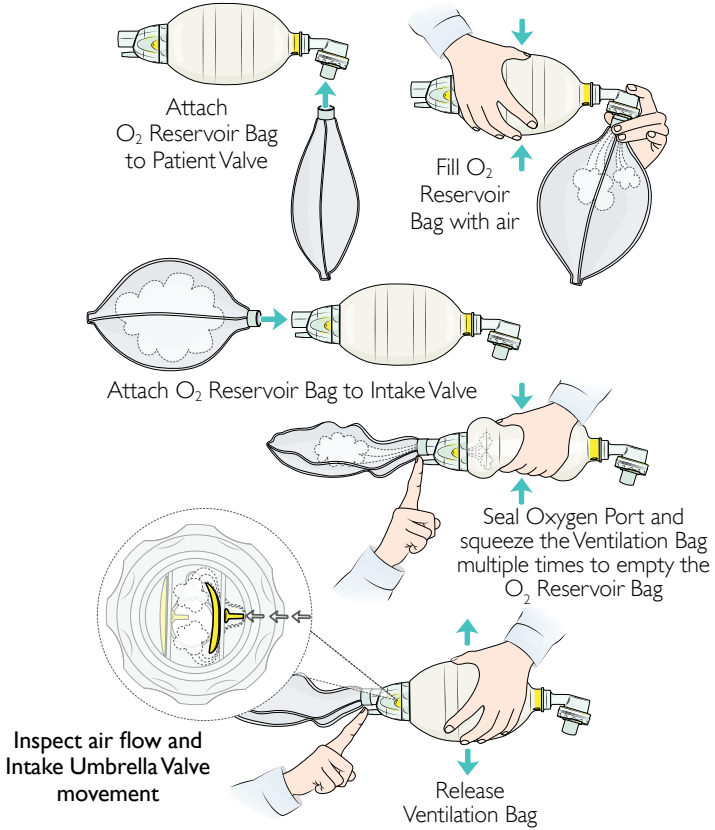
Testing the Patient Valve Disk Membrane



Testing the Oxygen Relief Umbrella Valve



Testing the Intake Umbrella Valve

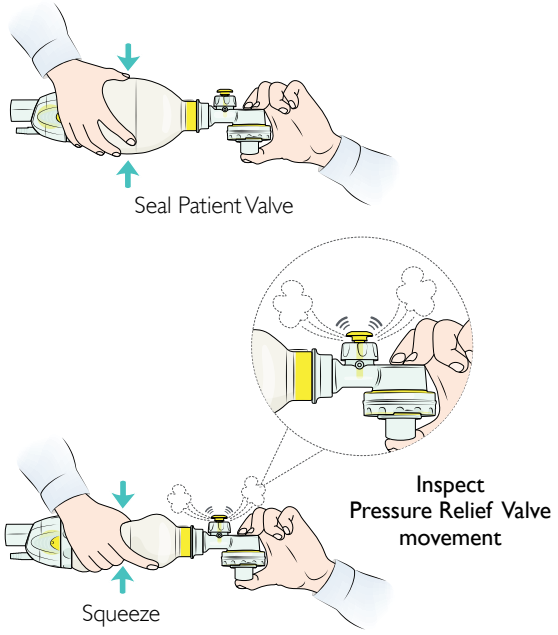


Testing the Pressure Relief Valve

Applies to Preterm and Paediatric models.

⚠ Caution

Ensure Pressure Relief Valve is functioning prior to use.



Operating the Laerdal Silicone Resuscitator with face mask:

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.

Operating the Laerdal Silicone Resuscitator with advanced airway:

1. Connect to external O_2 source, if applicable.
2. Connect to advanced airway of intubated patients.
3. Squeeze the Ventilation Bag in accordance to clinical protocol.
4. Observe patient chest rise during ventilation.
5. Allow patient to exhale.
6. Stop ventilation as required by clinical protocol.

⚠ Warning

Incorrect operation of the resuscitator can be hazardous.

Notes

- *An oxygen tube is not provided with the LSR. The oxygen connector fits oxygen tubes which comply with ISO 13544-2. Fit should be checked prior to use. The oxygen source should be able to be adjusted to provide a flow relevant to the LSR. See tables on pages 46-47 regarding achievable oxygen concentration at varying flows for more information.*
- *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.*

⚠ 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 LSR is stored as back-up in an area with potentially high levels of airborne pathogens, it should be considered to store the LSR in an air-tight container to avoid contamination.*

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 prior to cleaning and disinfecting.

- 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
- Do not disassemble the connectors from the Ventilation Bag or the O_2 Reservoir Bag. Do not disassemble the connectors from the Extension Tube, if used.
- Unscrew the Pressure Relief Valve (Preterm and Paediatric models), but do not disassemble any further.

Washing and Rinsing

The LSR and Masks must be cleaned before high-level disinfection or sterilisation.
The LSR and Masks 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 O_2 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.
⚠ Caution *Do not use rinsing and drying agents.*

To obtain high-level disinfection/sterilisation of the LSR and Masks, 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 O_2 Reservoir Bags which do not withstand high temperatures)*			
Steam Autoclaving (prevacuum-pulse)	Autoclave at 134 - 137 °C (273 - 279 °F)	3 min (+30s)	Allow parts to cool and dry
High-level Disinfection *(applies to all parts)*			
Sodium Hypochlorite	0.5% solution	20 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.

Reassembly

Reassemble LSR as shown in Assembly and Disassembly section.

Note

Perform function test after assembly and before patient use.

Warning

Disposable Oxygen Reservoir Bag (870702)

Designed for single patient use only. Do not reuse. Reuse will lead to risk of cross contamination. Laerdal is not responsible for any consequences of reuse.

Cautions

- *The resuscitator components must be cleaned and disinfected before next patient use.*
- *The use of cleaning and disinfection procedures not described in this section* may have adverse effects on the LSR material and/or performance and may not be effective for disinfecting the LSR.
- *The hard plastic components of the resuscitator and the mask cover are incompatible with polar solvents such as ethanol and isopropyl alcohol.*
- *Improper assembly of the LSR after reprocessing may affect performance.*
- *Accessories used for storing the LSR are not compatible with sodium hypochlorite.*

Laerdal Silicone Resuscitator meets the following Standards:

- EN 1789:2020
- ISO 10651-4:2002

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 Guidelines 2010, 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).

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.
℞ ONLY	Caution: Federal law restricts this device to sale by, or on the order of a physician (US).
LATEX	Not made with natural rubber latex
2	Single-use symbol

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: 15% to 95% rH
Lifetime Parameters	
Shelf-life	5 years
Expected Service Life	100 cycles of reprocessing
Resistance	
Expiratory resistance	Approximately 2.6 cm H_2O Measured with airflow of 50 lpm
Inspiratory resistance	With O_2 Reservoir: approx. 4.2 cm H_2O Without O_2 Reservoir: approx. 3.1 cm H_2O Measured with airflow of 50 lpm
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

Material Chart

Resuscitator		Accessories	
Parts	**Materials**	**Parts**	**Materials**
Mask	PSU, Silicone	Expiration Diverter	PSU, Silicone
Patient Valve (w/ Pressure Relief Valve)	PSU, Silicone (PPSU, Steel)	Silicone Extension Tube	PSU, Silicone, Viton
Ventilation Bag	PSU, Silicone, Viton	Hanging loop	Silicone
Intake Valve	PSU, Silicone	Wall Bracket	POM
Oxygen Reservoir	PC, PTFE, PVC	Wall Mount	ABS
		Display Case	ABS, PA, PP, Steel
		Disposable Oxygen Reservoir	PVC, PC

Adult Model

Ventilation Bag volume: 1600 ml.
Reservoir Bag volume: 2600 ml
Weight: Approximately 370 g
Dimensions: Approximately 370 mm x 132 mm x 132 mm
Dimension Display Case: W 291/326 mm x L 362 mm x H 136 mm
Dimension Compact Case: W 163/189 mm x L 237 mm x H 150 mm

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 O_2 Reservoir (without O_2 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
Weight: Approximately 230 g
Dimensions: Approximately 300 mm x 88 mm x 93 mm
Dimension Display Case: W 291/326 mm x L 362 mm x H 110 mm
Dimension Compact Case: W 163/189 mm x L 237 mm x H 150 mm

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 O_2 Reservoir (without O_2 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
Weight: Approximately 200 g
Dimensions: Approximately 280 mm x 72 mm x 85 mm
Dimension Display Case: W 291/326 mm x L 362 mm x H 110 mm
Dimension Compact Case: W 163/189 mm x L 237 mm x H 150 mm

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 O_2 Reservoir (without O_2 Reservoir)					
	20 x 40	20 x 60				
3	100 (98)	100 (97)				
8	100 (100)	100 (100)				
15	100 (100)	100 (100)				

Accessories

Catalogue #	Description
511700	LSR Wall Bracket
521100	Wall Mount for Paediatric and Preterm Display Case
572000	Wall Mount for Adult Display Case
850500	Expiration Diverter (OD 30 mm)
860300	Display Case, Paediatric
870120	LSR Hanging Loop
870600	LSR Display Case Complete Adult
870702	Disposable O_2 Reservoir
871000	Silicone Extension Tube

Spare Parts

Catalogue #	Description
510103	Cap for LSR Intake Valve, pack of 3
510404	LSR Intake Membranes, pack of 10
531901	LSR O_2 Reservoir 2.6 l
531906	LSR O_2 Reservoir 2.6 l
540103	LSR Lip Valve
540105	LSR Disk Membranes, pack of 10
551901	LSR O_2 Reservoir, 0.6 l

551906	Oxygen Reservior Bag 0.6 l, pack of 50
560200	LSR Patient Valve
850150	Preterm Bag, 240ml
851103	LSR Lock Clips, pack of 10
851250	Patient Valve with 35cm H_2O Pressure Relief Valve
851252	Pressure Relief Valve 35 cm H_2O
851350	Patient Valve with 35cm H_2O with Pressure Relief Valve and Lock Clip
860150	Paediatric Bag 500ml
870150	Adult Bag 1600ml
871950	Umbrella Valves, pack of 2
875400xx	Intake Reservoir Valve

Masks - Main Products

Catalogue #	Description
851500xx	LSR Silicone Mask no. 00
851600xx	LSR Silicone Mask no. 0/1
851700xx	LSR Silicone Mask no. 2
860220xx	Child Silicone Mask 3-4 with Multi Function Mask Cover
860221	Child Silicone Mask 3-4 without Multi Function Mask Cover
870220xx	Adult Silicone Mask 4-5+ with Multi Function Mask Cover

Spare Parts and Accessories

870221	Adult Silicone Mask 4-5+ without Multi Function Mask Cover
872220	Adult & Child Silicone Mask with Multi Function Mask Covers

Note

Catalog numbers ending with xx denotes local language configurations

Masks - Spare Parts/Accessories

Catalogue #	Description
865200	Multi Function Mask Cover for Mask 3-4
875200	Multi Function Mask Cover for Mask 4-5+

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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