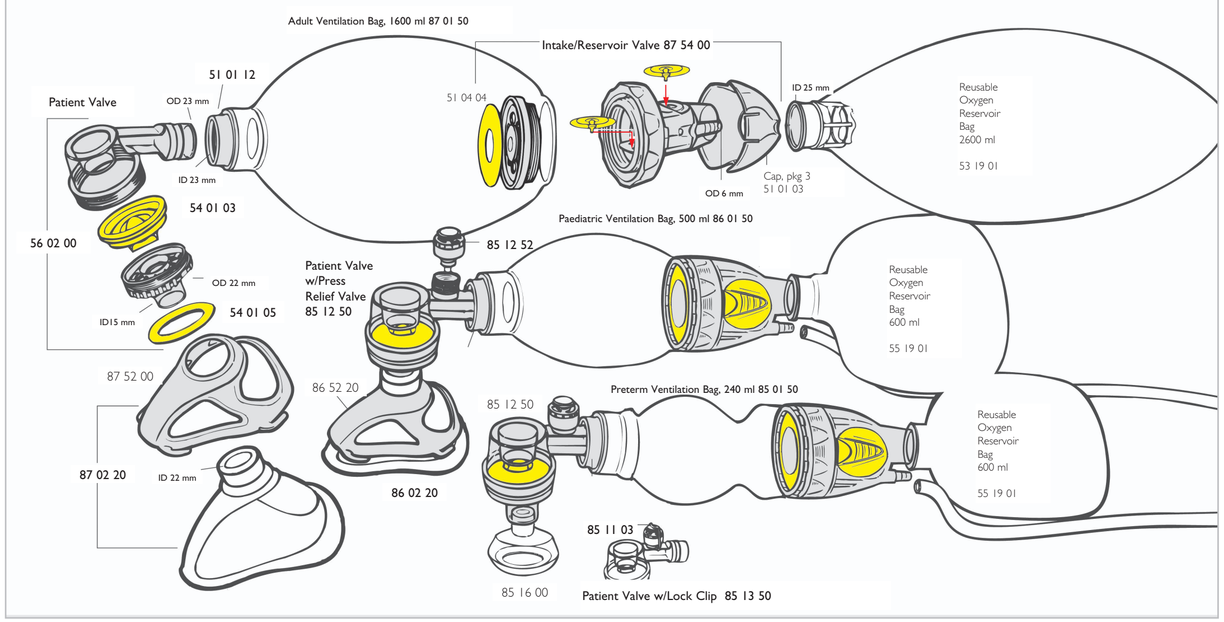
Laerdal Silicone Resuscitators Parts/Assembly Illustration



Optional Equipment/Accessories

Masks
85 15 00 Silicone Mask No. 00
85 16 00 Silicone Mask No. 0/1
85 17 00 Silicone Mask No.2
86 02 20 Silicone Child Mask 3-4 w/Multi-Function Mask Cover
87 02 20 Silicone Adult Mask 4-5+ w/Multi-Function Mask Cover
86 52 00 Multi-Function Mask cover 3-4
87 52 00 Multi-Function Mask cover 4-5

Patient Valves
56 02 00 Patient Valve
54 01 03 Lip Valve
54 01 05 Disk Membranes, pkg. 10
85 12 50 Patient Valve w/ Pressure Relief Valve
85 12 52 Pressure Relief Valve (35 cm H_2O)
85 13 50 Patient Valve w/Press Relief Valve and Lock Clip
85 11 03 Lock Clips, pkg. 10

Ventilation Bags/Intake Valve
85 01 50 Preterm Bag, 240 ml
86 01 50 Paediatric Bag, 500 ml
87 01 50 Adult Bag, 1600 ml
51 01 12 O-rings, pkg. 10
87 54 00 Intake Valve
87 19 50 Flap Valves, pkg 3
51 04 04 Intake membranes, pkg. 10
51 01 03 Cap, pkg. 3

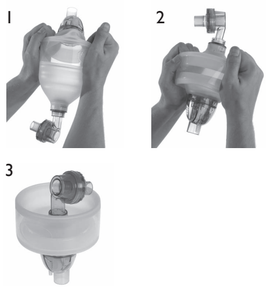
Reservoirs
53 19 01 O2 Reservoir 2.6 litres
55 19 01 O2 Reservoir, 0.6 litre

Containers
85 07 00 Display Case cpl., Preterm
86 03 00 Display Case cpl., Paediatric
87 06 00 Display Case cpl., Adult
86 04 10 Compact Case cpl. Preterm/Paediatric
86 04 20 Compact Case cpl. Adult

Optional Equipment/Accessories
85 05 00 Expiration Diverter (OD 30 mm)
87 10 00 Silicone Extension Tube (28 cm)
85 09 00 Manometer Connector
87 04 00 Laerdal Head Strap w/Attachment Ring
87 13 00 Attachment Ring f/Standard Head Strap
87 01 20 Hanging Loop
51 17 00 Wall Bracket
52 11 00 Wall Mount, Paediatric/Preterm displ. case
57 20 00 Wall Mount, ad. displ. case
87 05 50 Wall Poster reassembly guide
87 09 50 Directions for Use
53 19 07 Intake Valve Outer Part (23mm OD)
53 04 00 Airways, set of 4

Storage

For storage in small space, the Adult and Paediatric (but not the Preterm) ventilation bags may be folded as shown in fig. 1-2-3. Fold the Paediatric in same fashion as the Adult.



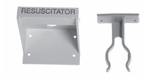
Long Term Storage
Laerdal Silicone Resuscitators and/or spare parts may be placed in long term storage. They should be periodically inspected and tested (at least yearly) according to the Function Testing section in this manual.

Storage Pouch (Not illustrated)
The Adult, Paediatric or Preterm resuscitator can be stored dust proof in the transparent resealable pouch. A loop through a metal eyelet permits hanging the pouch.

Compact Case
The Adult, Paediatric or Preterm resuscitator and accessories can be stored as illustrated.
The Compact Case can also be wall mounted.

Display Case (Not illustrated)
A fully assembled Adult, Paediatric or Preterm resuscitator can be stored for immediate use.
The Display Case may be hung on optional Wall Mount.

Wall Bracket
Separate Wall Bracket is available



Hanging Loop
The resuscitator can be hung ready for immediate use. For mounting Hanging Loop on the resuscitator, see separate instructions enclosed with the Hanging Loop.

Technical Specifications

Performance data may vary a great deal with the conditions under which they were obtained. Consequently, the findings in one test are not directly comparable with data found in another test unless test conditions were identical.

CE 0434 The product is in compliance with the essential requirements of Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC

Product meets the following Product Standards:
- EN/ISO 10651-4:2002, Lung ventilators- Particular requirements for operator-powered resuscitators
- ISO 8382: 1988 Resuscitators intended for Use With Humans.
- ASTM F 920 - 93, Standard Specification for Minimum Performance and Safety Requierments for Resuscitators Intended for Use With Humans.
- AS 2488-1995 Resuscitators intended for Use With Humans.

Operating environmental limits:
Operating condition: -18¡C to 60¡C.
(-0,4°F to 140°F)
15% to 95 %
Relative Humidity

Storage environmental limits:
Storage : -40¡C to 70¡C.
(-40°F to 158°F)
40% to 95 %
Relative Humidity

Dead space of Patient Valve:
Approx. 7,0 ml for all models

Expiratory resistance:
Approx. 2,6 cmH_2O
Measured with airflow of 50 lpm

Inspiratory resistance:
w/reservoir approx. 4,2 cmH_2O
w/o reservoir approx. 3,1 cmH_2O
Measured with airflow of 50 lpm

Attainable delivery volume
Adult: Approx. 800ml
Paediatric: Approx. 320ml
Preterm: Approx. 150ml

Test conditions: Compliance 0,02 l/cm H_2O,
Resistance 20 cm H_2O//l/s
No leakage;
Pressure Relief Valve overridden.

Feasible oxygen concentration
The feasible O_2 concentrations are approximated values and depend on the O_2 concentration delivered.

ADULT: Ventilation bag volume: 1600 ml
Reservoir bag volume: 2600 ml

Delivered O_2 concentrations under various test conditions:

O_2-flow lpm	Tidal vol. (ml) x bag cycling rate per min. O_2-concentrations (%) using reservoir (without reservoir).					
	400x12	400x24	600x12	600x24	1000x12	1000x24
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: Ventilation bag volume: 500 ml
Reservoir bag volume: 600 ml

O_2-flow lpm	Tidal vol. (ml) x bag cycling rate per min. O_2-concentrations (%) using reservoir (without reservoir).					
	20x40	20x60	150x20	150x30	300x12	300x24
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: Ventilation bag volume: 240 ml
Reservoir bag volume: 600 ml

O_2-flow lpm	Tidal vol. (ml) x bag cycling rate per min. O_2-concentrations (%) using reservoir (without reservoir).					
	20x40	20x60				
3	100 (98)	100 (97)				
8	100 (100)	100 (100)				
15	100 (100)	100 (100)				

Spontaneous breathing patient

O_2-flow lpm	Tidal vol. (ml) x bag cycling rate per min. O_2-concentrations (%) using reservoir (without reservoir).				
	Adult	Paediatric			Preterm
	600x20	300x20	150x25	20x60	20x60
3	44 (39)	66 (49)	99 (62)	100 (99)	100 (99)
8	81 (54)	98 (62)	99 (75)	100 (100)	100 (100)
15	96 (74)	98 (79)	99 (87)	100 (100)	100 (100)

Useful Life
Laerdal Silicone Resuscitator products, accessories and parts are carefully engineered and produced using materials that are suitable for the purpose. Care in accordance with these Directions for Use will help ensure that each product has a long and useful lifetime. (Tested in 100 cycle decontamination study)

Material Chart

Article	Component	Part	Material	
Storage Pouch			Polyethylene	PE
Compact Case			Polypropylene	PP
	Case		Acryl nitrilbutadiene styrene	ABS
	Partition wall		Polypropylene	PP
Display Case	Case		Styrene acrylonitril	SAN
	Window		Acryl nitrilbutadiene styrene	ABS
	Tray		Polyamide	PA
	Lock		Silicone rubber	SI
Bag	Bag		Polysulfone	PSU
	Valve Connector		Fluorelastomer	VITON
	O-Ring		Polysulfone	PSU
Patient Valve	Upper Housing		Polysulfone	PSU
	Patient side Housing		Silicone rubber	SI
	Lip Valve		Silicone rubber	SI
	Disk Membrane		Polysulfone	PSU
	Pressure Relief Valve	Stem	Polysulfone	PSU
		Housing	Stainless steel	
		Spring	Silicone rubber	SI
		Bush	Polysulfone	PSU
Intake Valve	Outer part		Polysulfone	PSU
	Inner part		Polysulfone	PSU
	Cap		Silicone rubber	SI
	Flap Valve		Silicone rubber	SI
	Intake Membrane		Polyvinyl chloride	PVC
O2 Reservoir Bag	Reservoir Bag		Polysulfone	PSU
	Coupling for bag		Silicone rubber	SI
Masks	No.00-0/1-2		Silicone rubber	SI
	No.3-4, 4-5+		Silicone rubber	SI
	No.0-1-2		Polysulfone	PSU
Optional Equipment			Stainless steel	
Mask Cover			Polyvinyl chloride	PVC
Lock Clip			Polycarbonate	PC
Head Strap w/Ring	Strap		Polysulfone	PSU
	Attachement Ring		Silicone rubber	SI
Expiration Diverter	Housing		Silicone rubber	SI
	Center gasket		Silicone rubber	SI
	External gasket		Polysulfone	PSU
Extension Tube	Tube		Polysulfone	PSU
	Coupling		Silicone rubber	SI
Manometer Connector			Acryl nitrilbutadiene styrene	ABS
Hanging Loop			Acetal	POM
Wall Mount				
Wall Bracket				

Shipping weights and dimensions

Cat. Nos.	Weights		Dimensions	
850050	340g	12 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
850051	380g	13 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
850053	830g	1 lb 13 oz	24 x 15 x 16 cm	9.4 x 5.9 x 6.3 in
850055	1640g	3 lb 10 oz	37 x 33 x 12 cm	14.6 x 13 x 4.7 in
860050	370g	13 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
860051	510g	1 lb 2 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
860052	440g	16 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
860053	920g	2 lb	24 x 15 x 16 cm	9.4 x 5.9 x 6.3 in
860055	1760g	3 lb 14 oz	37 x 33 x 12 cm	14.6 x 13 x 4.7 in
860056	390g	14 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
870050	520g	1 lb 2 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
870051	700g	1 lb 9 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
870052	625g	1 lb 6 oz	25 x 14,5 x 13 cm	10 x 5.7 x 5.1 in
870053	1060g	2 lb 5 oz	24 x 15 x 16 cm	9.4 x 5.9 x 6.3 in
870055	2090g	4 lb 10 oz	37 x 33 x 15 cm	14.6 x 13 x 4.7 in

PHT DEHP

The Laerdal oxygen reservoir bag used with this product contains DEHP.
The product is only intended for short-term/transient patient application and it is not directly, or through a liquid, in contact with the patient.
When cleaned and used according to these Directions for Use, there is no added risk involved when treating children or pregnant or nursing women.

ENGLISH Directions for Use

Laerdal Silicone Resuscitators

www.laerdal.com

4492 rev F Printed in Norway

Laerdal
helping save lives

Scope
This manual provides the information required to fully utilise the Laerdal" Silicone Resuscitator, and to help assure safe and trouble free operation over a maximum period of time. The Laerdal Silicone Resuscitator is available in three sizes: Adult, Paediatric and Preterm. The 3 sizes have many features and functions in common and are therefore described jointly whenever possible.
The detailed description of design and function should be read carefully by every user of the Laerdal Silicone Resuscitators.
It is mandatory that anyone who uses a manual resuscitator receive adequate instruction.
It is also helpful if the student practices bag-valve-mask ventilation on realistic training manikins, such as the Laerdal manikins.

Cautions and warnings
Read these Directions for Use carefully and become thoroughly familiar with the operation and maintenance of the Laerdal Silicone Resuscitator before using it.

- Resuscitators should only be used by persons who have received adequate training.
- Federal law (US) restricts this device to sale by or on the order of a physician.
- 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.
- Before first time use of the resuscitator parts and its accessories, decontamination is necessary.
- 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.
- Do not use parts other than genuine Laerdal parts. Use of non-Laerdal parts may affect safety and/or performance.
- 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 and may affect the material and/or performance.

Service
Laerdal Silicone Resuscitators are designed and engineered for utility and economy.
All components, parts and assemblies listed in the parts list may be replaced, when necessary, by the operator who is directed to carefully inspect them during decontamination procedures. Under normal conditions of use, no regularly scheduled factory service should be necessary. However, whenever a question arises we hope you will contact Laerdal Medical AS or an authorised Laerdal distributor.
Product specifications are subject to change without notice.

Limited warranty

Please refer to the Global Warranty statement for additional terms and conditions (www.laerdal.com)

Manufactured by:
LAERDAL MEDICAL AS
P.O. Box 377, N-4002 Stavanger
Tel. +47 51 51 17 00, Fax +47 51 52 35 57
E-mail: laerdal.norway@laerdal.no

Distributed in USA by:
LAERDAL MEDICAL CORPORATION
167 Myers Corners Road, P.O. Box 1840
Wappingers Falls, New York 12590-8840
Tel. (800) 431-1055, +1 (845) 297-7770
Fax (800) 227-1143, +1 (845) 298-4545
E-mail: customerservice@laerdal.com

Distributed in Canada by:
LAERDAL MEDICAL CANADA LTD.
151 Nashdene Rd., Unit #45
Toronto, ON, Canada, M1V 4C3
Tel. +1 (416) 298-9600
Fax +1 (416) 298-8016
E-mail: savelives@laerdal.ca

Indications for Use

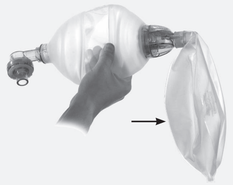
The Laerdal Silicone Resuscitator is a self-inflating manual resuscitator that is intended for patients requiring total or intermittent ventilatory support. The Laerdal Silicone Resuscitator provides positive pressure ventilation and allows spontaneous breathing either with a 22 mm ID (inner diameter) face-mask port, through an artificial airway or with a facemask that has a 15 mm OD (outer diameter) connection. The Preterm model is intended for patients below 2,5 kg (5,5 lb), the Paediatric model is intended for patients from 2,5 (5,5 lb) to 25 kg (55 lb), and the Adult model is intended for patients over 25 kg (55 lb).

Ventilation with ambient air
Resuscitator ventilation without supplemental oxygen is possible.

Ventilation with oxygen
The Laerdal Silicone Resuscitator can be connected to an O_2 source via the oxygen nipple. Concentrations delivered to the patient depend on O_2 flow rate, use (or non-use) of a Reservoir Bag and ventilation technique, e.g. tidal volume, ventilation frequency, time relations during compression-release cycles. **See Technical Specifications.**

Inhalation of supplemental oxygen
A patient who breathes spontaneously can inhale O_2 through the resuscitator with minimal resistance. Attachment of the reservoir increases O_2 concentration. **See Technical Specifications.**
The mask can be hand held or strapped to the face.

Safety when using oxygen
1. Build-up and transfer of high pressure to the patient is prevented since excess O_2 is vented to atmosphere over the outlet membrane of the Intake Valve.
2. When O_2 supply is insufficient, adequate ventilation volume is ensured by intake of ambient air over the intake membrane of the Intake Valve.
3. A Reservoir Bag that stays flat during the whole ventilation cycle is a visual indication that no, or little supplemental O_2 is being provided.



Pressure Relief Valve
The Preterm and Paediatric resuscitators feature a Patient Valve with a pressure limiting device mounted on the upper valve housing. If patient airway pressure exceeds 35 cm H_2O, the device opens to reduce the risk of stomach distention and barotrauma. A hissing sound can be heard when the device opens.

When higher airway pressures are necessary, the operator can keep the Pressure Relief Valve closed with the tip of index finger while squeezing the bag.

A Lock Clip (optional) can be used as an alternative to finger pressure.

Accessories

Masks
The Laerdal Silicone Resuscitator can be combined with the following mask types and sizes:
a) Circular Infant Masks 00, 0/1, 2
b) Laerdal Child Mask 3-4 and Laerdal Adult Mask 4-5+
For difficult facial anatomies the Multi-Function Mask Cover is used to assist in getting a better mask seal.

All masks are transparent to enable the user to observe the patient's face and lip colour and the temporary fogging caused by exhalations.

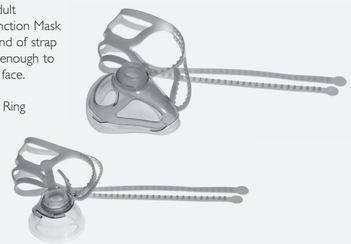
b)

Mask connection
The Patient Valve has a standard 15 (ID)/22(OD) mm patient port which connects to all standard masks or tube adapters. The Laerdal Masks 4-5+ and 3-4, plus the mask size 2, fit outside the patient valve connector. All other infant sizes fit inside, to reduce deadspace.

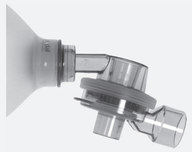
To use the Laerdal Head Strap

For Laerdal Child Mask 3-4 and Laerdal Adult Mask 4-5+, place the correct size Multi/Function Mask Cover over the mask connector. Fasten end of strap into the hooks on the cover. Tighten just enough to provide an airtight seal between mask and face.

For the Infant Mask 2, use the Attachment Ring supplied with the Laerdal Head Strap.



Expiration Diverter
An Expiration Diverter with two silicone gaskets can be snapped onto the Patient Valve.
The diverter provides an airtight seal to the valve housing but does not prevent the swivel function (possibility of horizontally rotating the bag without interfering with the position of mask or tube) of the valve connector.
The diverter will provide an airtight seal when expired air is free flowing. The use of the Expiration Diverter with a restriction device (e.g. PEEP Valve) may cause some air leakage around the silicone gasket of the Expiration Diverter.
Equipment for measuring, scavenging or monitoring expired gases, can be attached to the standard (30 mm OD) outlet port of the diverter.



Manometer Connector
If used insert the Manometer Connector between the Patient Valve and the mask or tube adapter.
Attach a manometer via tubing to the connector nipple (OD 6 mm) to monitor both inspiratory and expiratory pressures.

Extension Tube
The flexible Silicone Extension Tube may be used between ventilation bag and the Patient Valve.
This extension tube makes it easier to ventilate when the patient is being transported.
It also permits an operator to squeeze the bag against a bed, strecher or themselves.

Practical Operation

a) 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 (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 2000, the following applies. Adult for patients over 25 kg (5,5 lb), Paediatric for patients from 2,5 kg (5,5 lb) to 25 kg (55 lb) and Preterm for patients below 2,5 kg.

b) Either connect the Patient Valve directly to the patientxs tube, or choose the appro-priate size mask and attach it to the Patient Valve. Mask seal on difficult anatomies may be impro-ved by using the Multi Function Mask Cover (Mask size 3-4 and 4-5+ only).

c) Ventilate the patient by rhythmically compressing the bag for inspiration, allowing ample time between inspirations for patient's passive exhalation and bag re-expansion.

d) Follow local guidelines for resuscitation.

e) If the Patient Valve becomes contaminated with vomitus 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.

Caution:
Visually inspect and test valve function to ensure proper operation of the Laerdal Silicone Resuscitator prior to patient use. Improper assembly of the flap valves, intake membrane, disk membrane and lip valve may affect performance. Misassembly of two lip valves may cause inadvertant EEP (End Expiratory Pressure) or prevent proper patient exhalation.

Decontamination

Thorough decontamination of the resuscitator components and accessories is necessary after each use. To reduce risk of cross contamination, follow steps below.

1. **Washing and Rinsing**
Washing and rinsing is always the first step in the decontamination process.

A **Disassembly**
- Disassemble the LSR into individual parts as shown in the Parts Illustration in Directions for Use, to make surfaces accessible to cleaning
- Separate Expiration Diverter (if used) into its three parts
- Separate Patient Valve into its four main parts
- For Preterm and Paediatric models, unscrew top of Pressure Relief Valve, but do not disassemble this part any further.
- Separate Intake Reservoir Valve into its six parts

CAUTION: Leave connectors in the necks of Ventilation Bags, Extension Tube, and Reservoir Bags during the entire decontamination procedure.

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 non-validated cleaning, disinfecting or sterilisation methods may have adverse effects on the LSR material and/or performance.

Chose either the manual (I) or automatic (II & III) method below for cleaning the product.

I. Manual Cleaning

B Rinse parts in a sink under cold running water from a tap. Submerge parts in warm tap water (30-40¼C / 86-104¼F) ensuring that all surfaces are in contact with the warm water for at least 2 minutes before exposure to detergent.
C Immerse all parts in hot tap water (60-70¼C / 140-158¼F) containing a Dish Washing detergent[3].
Thoroughly clean all surfaces using a brush as necessary.
D Rinse all components free of detergent[4] in warm tap water (30-40¼C / 86-104¼F).
Dry the components thoroughly[5]
E Inspect all components to confirm that they are CLEAN and DRY.

II. Automatic Cleaning by Washer/Disinfector
Place parts in wire baskets. Cycle[1] : 90-95¼C (194-203¼F) for more than 12 seconds.
Total process time: approx. 52 min. [2] Use a Non-enzymatic alkaline detergent containing 2-5% NaOH[3].

III. Automatic Cleaning by Pasteurmatic Compact. [6] 30 min wash cycle at 32-43¼C (90-110¼F)

CAUTION: Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing, it might not be possible to achieve high-level disinfection or sterilisation of the device.

1. The cycle has been validated on a Getinge Model A8666 validated to HTM2030. Ninhydrin protein detection test was used to qualify the process (to determine if any soil remained on the parts). Use of alternative washer/disinfector must be validated.
2. Includes pre rinse, main wash, rinse, final rinse and drying.
3. The Washing Detergent used in the validation – Olympic Chemicals Sprayclean 2000 (Non-enzymatic alkaline detergent containing 2-5% NaOH). Alternative detergents must be validated to show cleaning efficacy and material compatibility. Method has been validated using a common available tenside based Dish Washing Detergent (Zalo Ultra manufactured by Lilleborg AS). A pH neutral detergent solutions or hydrogen peroxide-based formulations may also be used for manual cleaning but must be validated to show they effectively clean the components.
4. CAUTION: If detergent or disinfectant residuals are allowed to dry on the resuscitator parts, surfaces may become sticky, which may cause valve malfunction
5. Drying; the most effective method of drying is a fan assisted hot air cabinet, 50-70¦C (122-158¼F) for at least 30 minutes. Other drying methods may be used but must be validated to show they effectively dry the components. The Reservoir Bag must be dried by blowing air into the Reservoir Bag opening.
6. The cycle has been validated on a Pasteurmatic Compact from Olympic Medical.

2. **Disinfection/Sterilisation**
To obtain high-level disinfection/sterilisation of the resuscitator, the following 5 methods (I to V) have been validated and are recommended.
The sterilisation methods apply to all parts except reservoir bags, Head Straps, Wall Bracket, Storage Pouch and Containers. High-level disinfection methods apply to all parts.
Pasteurization applies to all parts except Wall Bracket, Storage Pouch and Containers

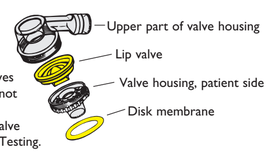
Method	Process parameters		Post-treatment
	Parameters/Concentration	Exposure time	
Sterilisation			
I. Steam Autoclaving (gravity- displacement)	Autoclave at 132-137¼C (270 - 279°F)	15min. 00s (+ 30s)	Allow parts to cool and dry.
II. Steam Autoclaving (prevacuum - pulse)	Autoclave at 134-137¼C (273-279¼F)	3min. 00s (+ 30s)	
High-level disinfection			
III. Cidex OPA (orthophtalaldehyde)	Conc.: 0,55% Ambient temperature	60 minutes	Remove traces of disinfectant by rinsing in warm tap water (30-40¼C / 86-104¼F) for minimum 2 minutes. Dry the components thoroughly
IV. Sodium Hypochlorite	Conc.: 0,5% Ambient temperature	20 minutes	
V. Pasteurization	Pasteurization cycle 70-75¼C (158-167¼F)	30 minutes	Dry the components thoroughly

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

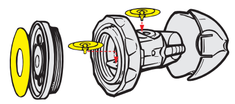
4. Reassembly
Reassemble resuscitator as shown in Parts/Assembly Illustration, in this Directions for Use.

Caution: Patient Valve reassembly

Make sure that only one Lip Valve Cat.No. 54 01 03 is installed.
If the valve housing does not tighten completely during reassembly, it may indicate that two lip valves have been mounted instead of one. Also, be sure not to mix the Disk Membrane for the Patient Valve with the Intake Membrane meant for the Intake Valve assembly. Test functions as described in Function Testing.



Intake Valve reassembly
Reassembly as shown right.

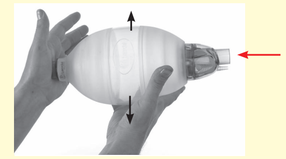


Function Testing

Test valve functions to ensure proper operation of the resuscitator after each disassembly-reassembly. An O_2 Reservoir Bag is needed to complete the test procedures described below:

1. Intake/Reservoir Valve

a) Compress the ventilation bag with one hand and close its neck opening with your other hand. Release the grip on the bag. Rapid bag reexpansion confirms efficient air intake.



b) Close the neck opening and try to compress the bag. If the bag cannot be compressed with rea-sonable force, or if bag compression forces the air out between your hand and neck of the bag, the valve efficiently prevents backward leakage of air.

2.1 Patient Valve

a) **Assure that a (single) Lip Valve has been installed in the Patient Valve.** Attach the Patient Valve to the bag. Hold a Reservoir Bag over the patient port connector pressing with your thumb on the reservoir bag connector.
Ensure tight seal between the patient port and Reservoir Bag.
Compress the bag with your other hand several times. Inspect that the Lip Valve opens during compression.

Filling of the Reservoir Bag in this set-up confirms that the Patient Valve efficiently directs air to the patient.

b) With the filled Reservoir Bag held firmly to the valve connector, compress the Reservoir Bag while watching the external Disk Membrane.

Lifting of the Disk Membrane from its seat confirms that air is correctly directed to atmosphere instead of being returned to the ventilation bag.

2.2 Patient Valve with Pressure Relief Valve

Close patient port connector with your thumb while compressing the bag several times. Visual and audible opening of the relief valve confirms its operation.

3. Reservoir Flap Valves
(located in the Intake Valve assembly.)

a) Do as described and shown in 2.1a above in order to fill the Reservoir Bag with ambient air. Attach reservoir to the Intake Valve and press on Reservoir Bag.
Compression of the Reservoir Bag and visual rise of the outlet Flap Valve confirms that the Reservoir Valve efficiently vents excessive gas to atmosphere.

b) Do as described and shown in 2.1a above in order to fill a Reservoir Bag with ambient air. Attach reservoir to the Intake Valve. With the Patient Valve in place and the reservoir attached to the Intake Valve, perform several compression-release cycles on the ventilation bag until the Reservoir Bag is flat and empty.
Rapid reexpansion of the ventilation bag after flattening of the Reservoir Bag confirms that the Reservoir Valve efficiently lets in ambient air.