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Manual Resuscitator (Ambu Bag)

Directions For Use

Manual resuscitator with oxygen tubing, reservoir bag and pressure limiting valve.

With mask or without mask.

With PEEP valve or without PEEP valve.

- ☐ **Reusable Silicone manual resuscitator**
- ☐ **Disposable PVC manual resuscitator**
- ☐ **Disposable SEBS manual resuscitator**

- ☐ **Adult**
- ☐ **Pediatric (Child)**
- ☐ **Infant**

Non-sterile, 100% Latex Free.

Intended use

The resuscitator is intended for pulmonary resuscitation.

The range of application for each version is:

- Adult: adults and children.
- Pediatric: children and infants.
- Infant: infants and neonates.

The resuscitator can be used as normal for continued oxygen supply and assisted ventilation.

Item Code List

Type	Size	Ref	Contents
silicone reusable	adult	323-1-12AP	silicone resuscitator silicone mask oxygen reservoir bag oxygen tubing 2.1M pressure relief valve
silicone reusable	pediatric	323-2-12AP	
silicone reusable	infant	323-3-12AP	
silicone reusable	adult	323-1-12AH	
silicone reusable	pediatric	323-2-12AH	
silicone reusable	infant	323-3-12AH	
silicone reusable	adult	323-1-12AP/PV	silicone resuscitator silicone mask oxygen reservoir bag oxygen tubing 2.1M pressure relief valve PEEP valve
silicone reusable	pediatric	323-2-12AP/PV	
silicone reusable	infant	323-3-12AP/PV	
silicone reusable	adult	323-1-12AH/PV	
silicone reusable	pediatric	323-2-12AH/PV	
silicone reusable	infant	323-3-12AH/PV	
PVC disposable	adult	324-1-12AP	PVC resuscitator PVC mask oxygen reservoir bag oxygen tubing 2.1M pressure relief valve
PVC disposable	pediatric	324-2-12AP	
PVC disposable	infant	324-3-12AP	
PVC disposable	adult	324-1-12AH	
PVC disposable	pediatric	324-2-12AH	
PVC disposable	infant	324-3-12AH	
PVC disposable	adult	324-1-12AP/PV	PVC resuscitator PVC mask oxygen reservoir bag oxygen tubing 2.1M pressure relief valve PEEP valve
PVC disposable	pediatric	324-2-12AP/PV	
PVC disposable	infant	324-3-12AP/PV	
PVC disposable	adult	324-1-12AH/PV	
PVC disposable	pediatric	324-2-12AH/PV	
PVC disposable	infant	324-3-12AH/PV	
SEBS disposable	adult	398-1-12AP	SEBS resuscitator PVC mask oxygen reservoir bag oxygen tubing 2.1M pressure relief valve
SEBS disposable	pediatric	398-2-12AP	
SEBS disposable	infant	398-3-12AP	
SEBS disposable	adult	398-1-12AH	
SEBS disposable	pediatric	398-2-12AH	
SEBS disposable	infant	398-3-12AH	
SEBS disposable	adult	398-1-12AP/PV	SEBS resuscitator PVC mask oxygen reservoir bag oxygen tubing 2.1M pressure relief valve PEEP valve
SEBS disposable	pediatric	398-2-12AP/PV	
SEBS disposable	infant	398-3-12AP/PV	
SEBS disposable	adult	398-1-12AH/PV	
SEBS disposable	pediatric	398-2-12AH/PV	
SEBS disposable	infant	398-3-12AH/PV	

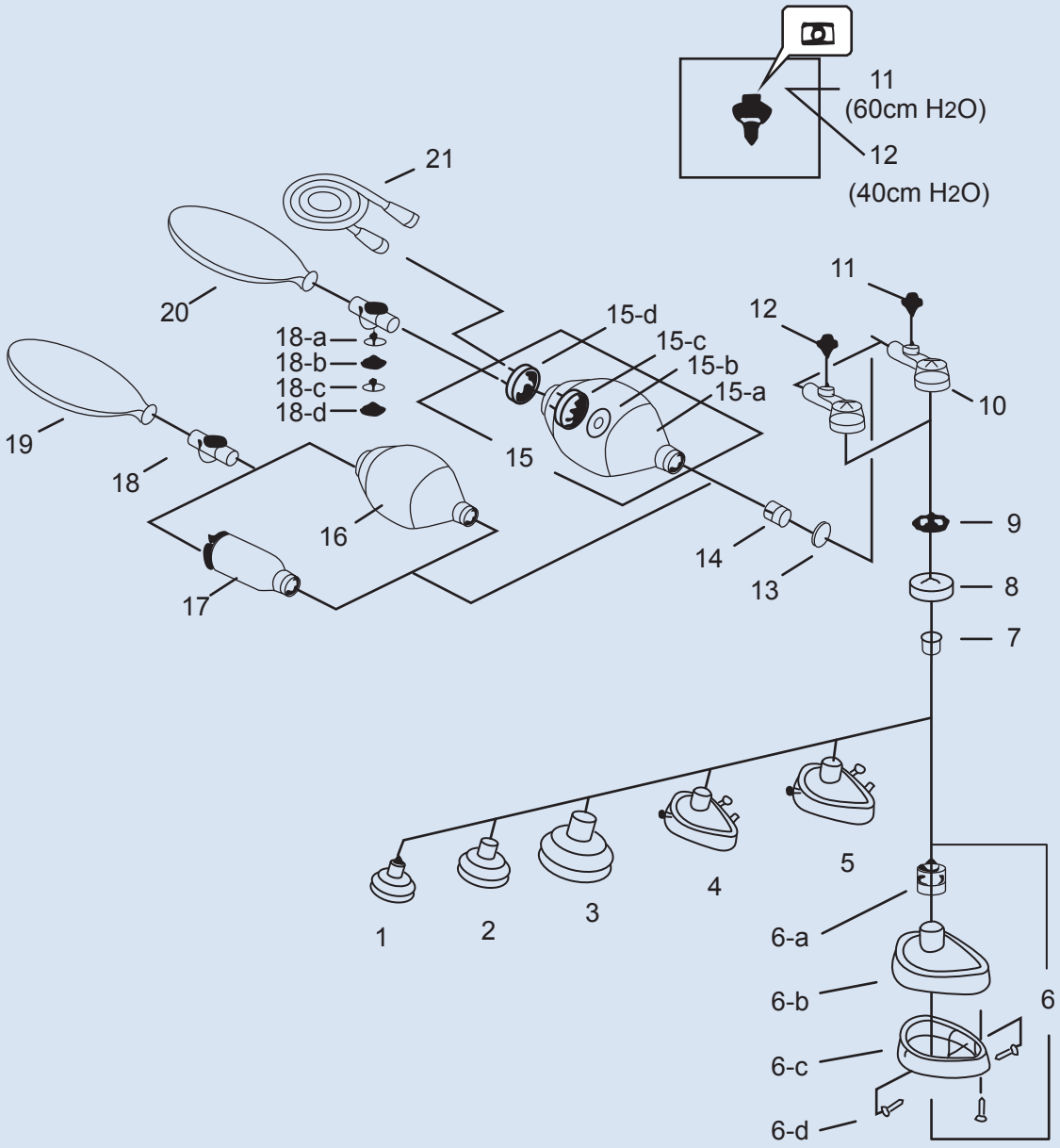
Name of parts for silicone manual resuscitator

Silicone manual resuscitator (silicone resuscitation bag, silicone mask)			
Item No.	Name	Material	Remark
1	Face mask	Silicone	Neonate 0#
2	Face mask	Silicone	Infant 1#
3	Face mask	Silicone	Child 2#
4	Face mask	Silicone, PC	Adult-S 3#
5	Face mask	Silicone, PC	Adult-M 4#
6	Face mask	Silicone, PC	Adult-L 5#
6-a	Mask connector	Silicone	
6-b	Mask cover	PC	
6-c	Mask cushion	Silicone	
6-d	Bolt	Silicone	
7	Connector	PC	
8	Lid	PC	
9	Patient valve disk	Silicone	
10	Patient valve	PC	
11	Pressure Limiting valve	PC, silicone, steel	60cmH_2O
12	Pressure Limiting valve	PC, silicone, steel	40cmH_2O
13	O-ring	Silicone	
14	Bag connecter	PC	
15	Adult resuscitation bag	Silicone	
15-a	Resuscitation bag	Silicone	
15-b	Intake valve disk	Silicone	
15-c	Cap	PC	
15-d	Intake valve	PC	Can be (all in 1 inlet valve)
16	Pediatric resuscitation bag	Silicone	
17	Infant resuscitation bag	Silicone	
18	Inlet valve	PC	Can be (all in 1 inlet valve)
18-a	Inlet valve disk	Silicone	
18-b	Valve stand	PC	
18-c	Excess valve disk	Silicone	
18-d	Cover	PC	
19	Reservoir bag 1600ML	EVA, PP	
20	Reservoir bag 2000ML	EVA, PP	
21	Oxygen tubing	PVC	

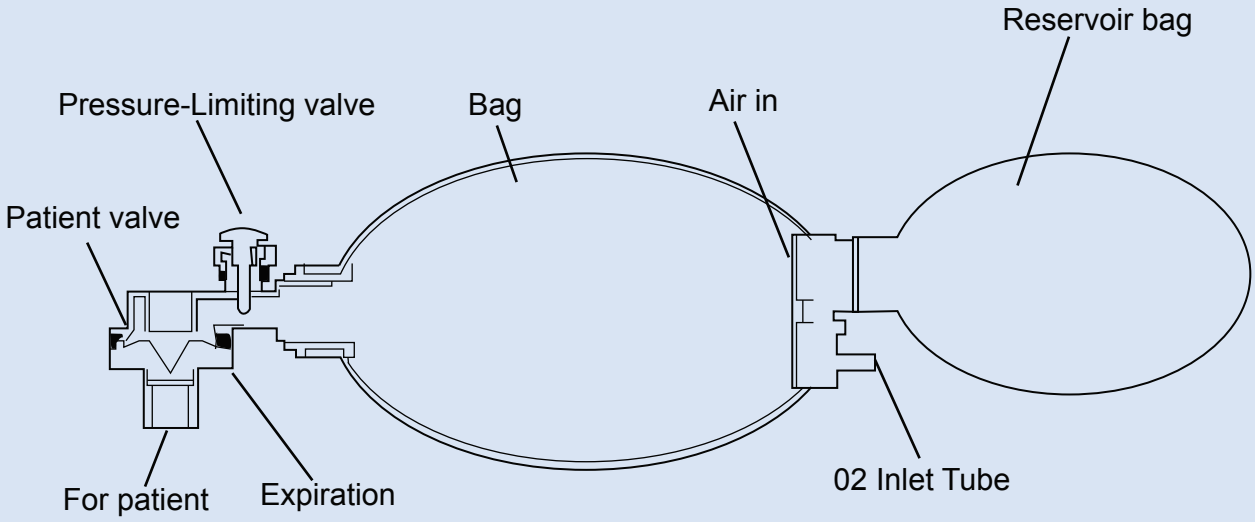
Name of parts for PVC/SEBS manual resuscitator

PVC/SEBS manual resuscitator (SEBS/PVC resuscitation bag, PVC mask)			
Item No.	Name	Material	Remark
1	Face mask	PVC	Neonate
2	Face mask	PVC	Infant
3	Face mask	PVC	Pediatric
4	Face mask	PVC	Adult-S
5	Face mask	PVC	Adult-M
6	Face mask	PVC	Adult-L
6-a	/	/	
6-b	Mask cover	PVC	
6-c	Mask cushion	PVC	
6-d	/	/	
7	Connector	PC	
8	Lid	PC	
9	Patient valve disk	Silicone	
10	Patient valve	PC	
11	Pressure Limiting valve	PC, silicone, steel	60cmH_2O
12	Pressure Limiting valve	PC, silicone, steel	40cmH_2O
13	/	/	
14	Bag connecter	PC	
15	Adult resuscitation bag	PVC / SEBS	
15-a	Resuscitation bag	PVC / SEBS	
15-b	Intake valve disk	Silicone	
15-c	Cap	PC	
15-d	Intake valve	PC	Can be (all in 1 inlet valve)
16	Pediatric resuscitation bag	PVC / SEBS	
17	Infant resuscitation bag	PVC / SEBS	
18	Inlet valve	PC	Can be (all in 1 inlet valve)
18-a	Inlet valve disk	Silicone	
18-b	Valve stand	PC	
18-c	Excess valve disk	Silicone	
18-d	Cover	PC	
19	Reservoir bag 1600ML	EVA, PP	
20	Reservoir bag 2000ML	EVA, PP	
21	Oxygen tubing	PVC	

Assembly structure:



Resuscitator function



Caution ⚠

1. This product must be used by personnel thoroughly trained in the techniques of pulmonary resuscitation.
2. Clear patient's airway before using manual resuscitator.
3. Always check for proper function of resuscitator.
4. Verify proper valve action. Verify patient is being ventilated by observing alternate rise and fall of the patient's chest and color of lips and face during resuscitation.
5. Always make functional test of the resuscitator after unpacking and assembly.
6. Do not use the resuscitator in toxic or hazardous atmospheres.
7. Oil or grease should not be used in close proximity to oxygen equipment – fire may result.
8. Do not smoke or use open flames when oxygen is in use – fire may result.
9. PVC/SEBS manual resuscitator are disposable. It is for use on a single patient only. No reprocessing must be done. If reusable may cause cross infection between the patients.
10. Store in a cool, dry and dark place. Avoid direct sunlight.

Set up manual resuscitator:

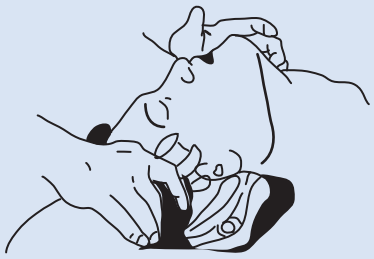
Full extend the bag of resuscitator (adult and pediatric version). Prior to using the resuscitator. Visually proper valve action while squeezing the resuscitator. Connect patient valve into outlet of mask. If resuscitating with high oxygen concentration, full extend the oxygen tube, attach oxygen nozzle adapter to proper oxygen source. Connect reservoir bag. Set oxygen flow not to exceed 15 LPM or on the order of a physician.

Test for correct function

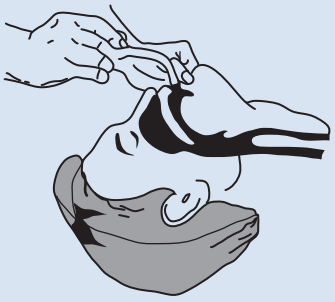
1. Connect a 1.5 liter test lung to the patient connector. Squeeze and release the resuscitator several times. And check that the test lung fills. During continuous ventilation, expansion and relaxation of the test bag must be visible. If not, check the inlet valve shutter and the patient valve shutter.
2. Close the pressure limiting valve and the patient connector with a thumb while compressing the resuscitator bag firmly to check tightness and proper valve fitting.
3. Open the pressure limiting valve and close the patient connector with a thumb. The pressure limiting valve should now be activated and it should be possible to hear the expiratory flow from the valve.
4. Reservoir bag: Supply a gas flow of 3.0 L/min to oxygen tube. Check that the reservoir fills. If not, check the integrity of the two valve shutters, or for a torn reservoir or a blocked oxygen tube.

Operating instructions

1. Open mouth, clear airway of all foreign matter and fluids. The use of an Emergency Aspirator is recommended. Tilt head fully backwards and push the jaw upwards with neck stretched to open the airway.

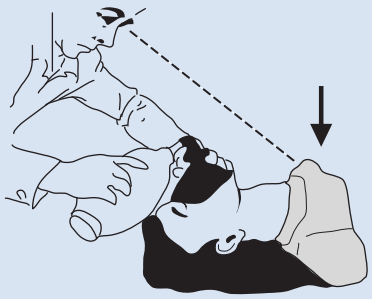


2. To assist ventilation it may be beneficial to insert an artificial airway. Be careful that it does not push the tongue back and thus obstruct the throat.



3. Hold mask tightly to victim's face, covering mouth and nose, tilt head fully backwards, mask-holding hand lifting jaw forward. Squeeze the bag smartly and watch chest expand.

4. Release pressure on the bag suddenly and allow the chest to deflate. Repeat 12-20 times per minute, or 30 times in the case of infants.



If continued resistance to insufflation is encountered, check for airway obstruction or correct the backward head tilt. If adequate ventilation is not achieved with the resuscitator, immediately revert to expired air ventilation (mouth-to-mouth, or mouth-to-nose).

5. The correct ventilation frequency may vary. Please follow the current ventilation frequency recommended by national or international guidelines.
6. If the patient vomits during mask ventilation, immediately clear the patient's airways of vomitus, then freely compress the bag a few times before resuming ventilation.
7. Adult version: The pressure limiting valve is open at 60 cmH2O.
   Pediatric and infant version: The pressure limiting valve is open at 40 cmH2O.

   ⚠ ***Caution:*** ***A hissing sound can be heard when the device opens.***
8. If higher pressures are required, press and spin the button while squeezing the bag, the pressure limiting valve is overridden.

   ⚠ ***Warning: High ventilation pressures may cause lung rupture or stomach distension on certain patients.***
9. Administer oxygen reference to "**Specifications**" or according to medical indications.

Specifications

Oxygen Concentrations					
Liters/min	3	5	10	10	4
Breathing frequency	12	12	12	20	30
Inflation Volume (ml)	500	500	500	250	40
With reservoir (%)	60	86	98	98	98
Without reservoir (%)	34	47	66	70	85

	Infant	Pediatric	Adult
Body weight	≤10kg	10kg～40kg	＞40kg
Stroke volume	150ml	400ml	800ml
Resuscitator volume	280ml	600ml	1650ml
Dimensions (Length x Diameter)	135 x 75mm	146 x 100mm	212 x 131mm
Resuscitator weight	350g	410g	600g
Pressure limiting valve	40 cmH2O	40 cmH2O	60 cmH2O
Dead space (patient valve)	7ml	7ml	7ml
Inspiratory resistance	＜5 cmH2O (at 50 L/min)		
Expiratory resistance	＜5 cmH2O (at 50 L/min)		
Bag reservoir volume	1600ml	1600ml	2000ml
Patient connector	ISO5356-1: Ø22/15mm		
Recommended operating temperature: -18℃～+50℃			
Storage	-40℃～+60℃		

Disassemble:

Silicone resuscitator reference above **“Assembly structure”**: Unscrew “8” from “10”, remove “10” from “14”, unscrew “15-c” from “15-d”. **Do not disassemble “7” from “8”.**

Assemble:

Silicone resuscitator reference above **“Assembly structure” and “Resuscitator function”.**

Clean and sterilize:

The silicone resuscitator (except O2 tubing and reservoir bag) wash with 0.2% Javelwater and Rinse in clean water, then send for autoclaving 15 minutes up to 134 ℃.

The silicone Resuscitator (silicone mask, bag and valves) are reusable items.

The oxygen tubing and Reservoir bag are disposable items, It must be replace before reuse.

The resuscitator conforms to the standard: ISO 10651-4

It also conforms to Directive 2007/47/EC and Council Directive MDD/93/42/EEC concerning Medical Devices.

Respiratory Care

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