

Silicone Ambu Bag

Cat.No. 131621-131626

Intended use

Silicone Ambu Bag, also called Bag valve mask (BVM), Manual resuscitator, is a durable manual medical device used for resuscitation, providing life-saving manual ventilation during emergencies like respiratory arrest and CPR.

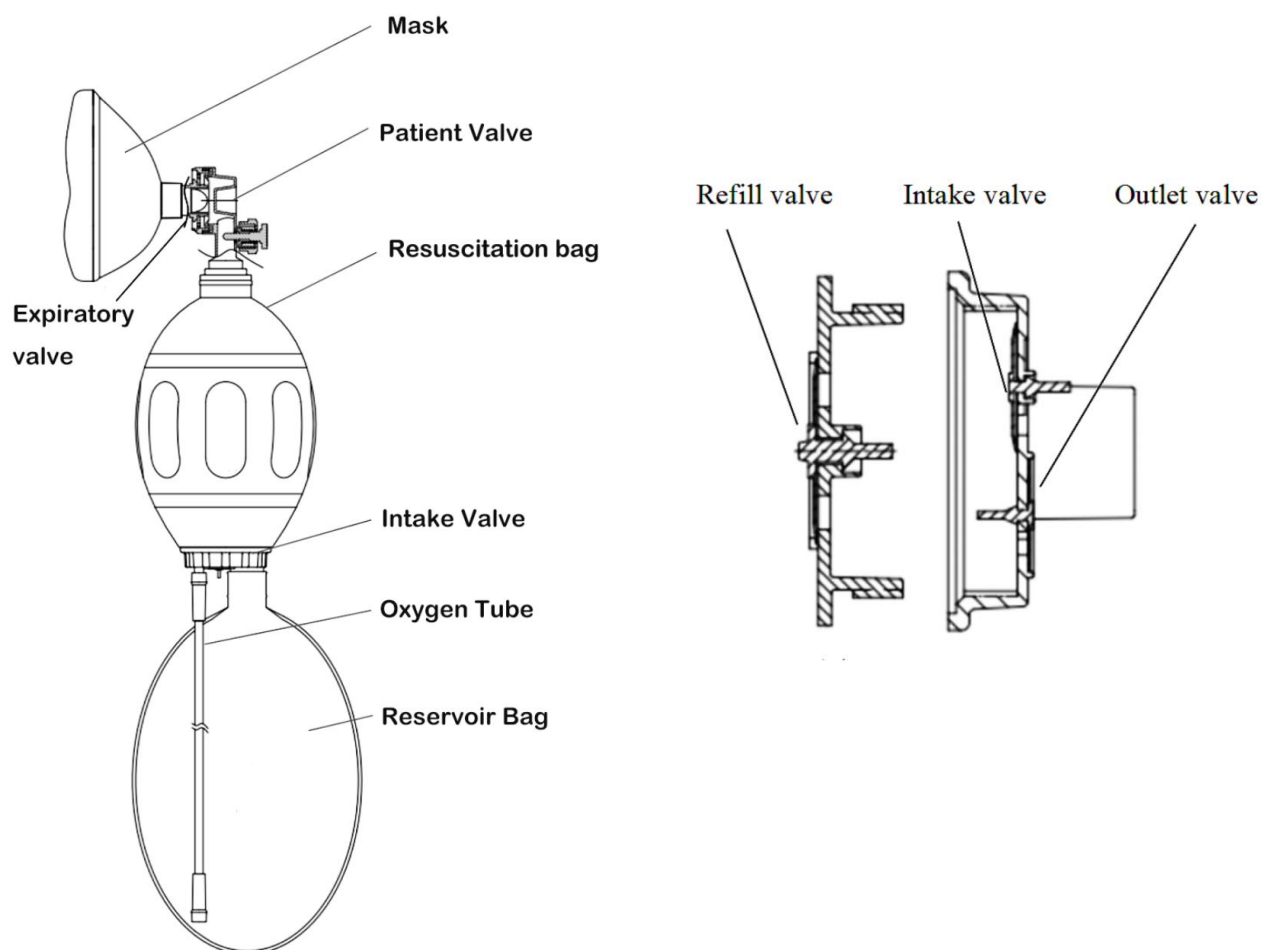
Component

The Reusable manual resuscitator is composed of mask, patient valve, resuscitation bag, intake valves, reservoir bag, oxygen tube.

Type

- Neonate/Infant, size 0, 1
- Pediatric, size 2
- Adult, size 3, 4, 5

Schematic diagram for Resuscitator



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Accessory & Material

Accessories	Material
Mask	Silicone, PC
Patient valve	PC
Resuscitation bag	Silicone
Intake Valves	PC
Oxygen tube	PVC
Reservoir Bag	EVA film, PP

Specification

	Infant	Pediatric	Adult
Body weight	≤10kg	10kg~40kg	≥40kg
Stroke volume	≥20ml	≥150ml	≥600ml
Resuscitator volume	280ml±100ml	550ml±200ml	1500ml±200ml
Dimensions(Length x Diameter)	225mmx85mm	262mmx105mm	325mmx131mm
Pressure limiting valve	30cm H ₂ O~45cm H ₂ O	35cm H ₂ O~50cm H ₂ O	40cm H ₂ O~60cmH ₂ O
Dead space(patient valve)	≤7ml	≤20ml	≤65ml
Inspiratory resistance	≤5cmH ₂ O (at 50 L/min)		
Expiratory resistance	≤5cmH ₂ O (at 50 L/min)		
Bag reservoir volume	1600ml	1600ml	2000ml
Patient connector	ISO5356-1:Φ22/15mm		
Recommended operating condition	-18℃~+50℃, 15%r.h~95%r.h		
Storage	-40℃~+60℃, 40%r.h~95%r.h		
Supplementary oxygen and delivered oxygen concentration (≥85%)	V _T =60ml Frequency: 20BPM Flow rate: 15L/min	V _T =150ml Frequency: 25BPM Flow rate: 15L/min	V _T =600ml Frequency: 25BPM Flow rate: 15L/min

Technical Requirements

1. Resuscitation bag

1.1 Appearance

The surface of the resuscitator and accessories shall be smooth, free of burrs, free of mechanical impurities and foreign objects, spots, air bubbles, and the oxygen tube shall be transparent.

1.2 Dimension

Patient connection port connector

The patient connection port connector of the resuscitator shall be a coaxial 15 mm socket and 22 mm cone connector conforming with ISO 5356-1: 2015.

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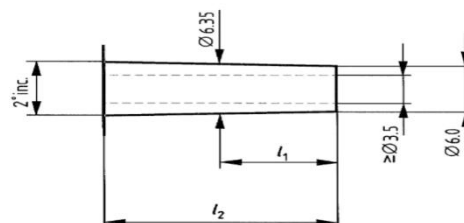
Intake connector of intake valves

Outer diameter shall be $25 \pm 0.2 \text{ mm}$; Inner diameter shall be $21.8 \pm 0.2 \text{ mm}$; It shall be firmly connected with the reservoir bag connector.

Oxygen tube connector of intake valves

Oxygen tube connector shall meet the requirement of EN13544-

2:2000; The outer diameter of the end $\phi 6.0 \pm 0.15 \text{ mm}$; inner diameter $\geq \phi 3.5 \text{ mm}$; The length $l_2 \geq 12 \text{ mm}$, outer diameter of the part, which is $l_1 = 10 \text{ mm}$ away from the end: $\phi 6.35 \pm 0.2 \text{ mm}$.



Resuscitation bag Volume

Adult model: $1500 \pm 150 \text{ ml}$

Pediatric model: $550 \pm 150 \text{ ml}$

Infant model: $280 \pm 100 \text{ ml}$

1.3 Refill valve/Intake valve/Outlet valve/Expiratory valve

Refill valve/Intake valve/Outlet valve/Expiratory valve shall not have provision for manual operation, and not be capable of being inadvertently blocked with a hand or flat surface, and their functions are normal.

1.4 Delivered oxygen concentration

The resuscitator with its accessories shall be capable of providing a delivered oxygen concentration of at least 85 % (V/V) when connected to an oxygen source supplying not more than 15 l/min.

1.5 Expiratory resistance

In the absence of positive end-expiratory pressure devices, the pressure generated at the patient connection port shall not exceed 5 hPa ($\approx 5 \text{ cmH}_2\text{O}$).

1.6 Inspiratory resistance

The pressure at the patient connection port shall not exceed 5 hPa ($5 \text{ cmH}_2\text{O}$).

1.6 Gas source excessive flow

Operate the BVM at a flow rate of 30 L/min, and the positive end expiratory pressure shall not exceed 6 hPa ($\approx 6 \text{ cmH}_2\text{O}$).

1.7 Patient valve leakage - Forward leakage

There is no forward leakage on the product except for the pressure relief valve.

1.8 Resuscitator deadspace and repeated breathing

The deadspace shall not exceed 5 ml + 10 % of the minimal guaranteed tidal volume, and excessive repeated breathing shall not occur during spontaneous breathing. For an intended patient ideal body mass less than or equal to 5 kg, the resuscitator deadspace shall not exceed 7 ml.

2. Mask

2.1 Dimension

Model	volume	Size of Mask		
		Length(L)	Width(W)	Height(H)
0#	27.5 ± 15	$65 \text{ mm} \pm 10\%$	$49 \text{ mm} \pm 10\%$	$46 \text{ mm} \pm 15\%$
1#	59.2 ± 15	$80 \text{ mm} \pm 10\%$	$60.5 \text{ mm} \pm 10\%$	$53 \text{ mm} \pm 15\%$
2#	101.9 ± 20	$95 \text{ mm} \pm 10\%$	$72 \text{ mm} \pm 10\%$	$60.5 \text{ mm} \pm 15\%$
3#	146.8 ± 25	$106 \text{ mm} \pm 10\%$	$80 \text{ mm} \pm 10\%$	$65.5 \text{ mm} \pm 15\%$
4#	220.5 ± 30	$122 \text{ mm} \pm 10\%$	$92.5 \text{ mm} \pm 10\%$	$73 \text{ mm} \pm 15\%$
5#	303 ± 30	$135 \text{ mm} \pm 10\%$	$102.5 \text{ mm} \pm 10\%$	$79 \text{ mm} \pm 15\%$

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2.2 Mask connector fit tightness

Under a temperature of $(35\pm 3)^{\circ}\text{C}$ and relative humidity of at least 80% , the face mask connector matched a 22 mm cone connector, or a 15 mm socket connector conforming with ISO 5356- 1:2015, after 1 min of engagement without activation of any disengagement mechanism, apply for 10 s an axial separation force of $(5\pm 1)\text{N}$, and confirm that the assembled connectors do not become disconnected.

2.3 Mask tightness

The connections of the mask are firm and reliable, and there shall be no air leakage.

2.4 Airflow resistance (pressure drop)

When the flow rate of the mask is 30L/min, the pressure drop at both ends of the mask shall not exceed 0.1kPa.

3. Oxygen tube

3.1 The length of oxygen tube shall be $200\pm 20\text{cm}$.

3.2 Inner diameter of oxygen tube connector

The inner diameter of the mouth of the oxygen tube connector (excluding the chamfer) is $4.7\pm 0.4\text{mm}$.

3.3 Assembly tension of oxygen tube connector and the connector of device for oxygen tube

The fitting length between the oxygen tube connector and the connector of device for oxygen tube is $10\pm 0.5\text{mm}$. Apply the axial tension of $10\pm 0.5\text{N}$ and at temperature $45\pm 2^{\circ}\text{C}$ for 1min, which shall not fall off.

3.4 Adhesion between oxygen tube and oxygen tube connector

The oxygen tube is connected to the oxygen tube connector. Apply the axial tension of 30N for 15s, which shall not fall off, be broken, or loosen.

3.5 The tension of the oxygen tube

Apply 30N axial tension for 15s, the oxygen tube shall not break.

3.6 Ventilation performance of oxygen tube

Under normal pressure, the flow rate of oxygen tube shall be not less than 15L/min.

3.7 Oxygen tube connector and the connector of device for oxygen tube

The fitting length between the oxygen tube connector and the connector of device for oxygen tube is $10\pm 0.5\text{mm}$. Under the 100kpa pressure and at temperature $45\pm 2^{\circ}\text{C}$ for 10mins, there shall be no leakage or not fall off on oxygen tube.

3.8 Oxygen tube airflow resistance

Under the flow rate of 5L/min, the pressure increment per meter of oxygen tube length shall not exceed 2.0kpa.

3.9 Oxygen tube deflation resistance

Under the flow rate of $10\pm 0.5\text{L/min}$, bend the tail of the oxygen tube 10cm into a U shape and place it in a parallel groove that is three times the diameter of the oxygen tube. After stabilizing for 10 minutes, the flow rate should not drop more than 25% of the initial flow rate.

3.10 Bending resistance of oxygen tube

The oxygen tube was bent 10 times at -18°C , normal laboratory temperature, and 50°C , respectively. The tube shall not be broken, and the inner wall of the lumen shall not be bonded.

3.11 Pressure strength of Oxygen tube connector and the connector of device for oxygen tube

The fitting length between the oxygen tube connector and the connector of device for oxygen tube is $10\pm 0.5\text{mm}$. Under the 200kpa pressure for 10mins, there shall be no leakage or not fall off on oxygen tube.

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4. Reservoir Bag

4.1 Reservoir bag volume

Adult model: 2000±200ml

Child&Infant model: 1600±200ml

4.2 Connector size of reservoir bag

The inner diameter of the end face is 25.4±0.3mm, the reservoir bag connector matching with the connector of intake valve cooperate normally, and are not compatible with the connector of ISO 5356-1: 2015.

4.3 Leakage of reservoir bag

After the reservoir bag is filled with water, the bag body and each connection shall not leak.

Shelf life: 5years