STURDY INDUSTRIAL CO., LTD.

PVC RESUSCITATOR KIT

(DISPOSABLE)

REF
SR-011
SR-012
SR-013

Instruction for Use

For use by CPR trained personnel only.

The resuscitator must be unpacked and unfold from its compressed form (applicable to adult size bags), fit the face mask, install reservoir system and all other prescribed equipments for immediate use.

- The integrity of resuscitator kits & their function must be inspected periodically to ensure instant availability for emergency use.

Note：Unfold compressed bag by pulling patient valve & air intake valve, avoid pulling the reservoir system.

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NON STERILE

CE 2460

Table of Contents

1.Warning / Cautions

- Use only as directed. Improper usage or unauthorized modification of this product may result in user or patient injury.
- Resuscitator should not be used in toxic or hazardous atmosphere.
- Do not allow smoking or use unit near sparking equipment, open flame, oil or other flammable chemicals. Turn off oxygen cylinder when not in use.
- Use of PEEP may have an adverse effect such as barotraumas and/or reduced cardiac output. Only qualified medical personnel trained in the use of PEEP should administer PEEP with this resuscitator.
- Remove the oxygen reservoir and reservoir valve if supplemental oxygen is not being administered. Failure to do so will effect refill rate and maximum ventilation frequency capabilities.
- Do not attempt to use resuscitator once it fails function test and/or visual examinations.
- Do not attempt to disassemble the pressure relief valve to prevent potential damage.
- Use only Topster (Sturdy) components, when replacement is required.
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- The parts of device should be discarded with following the local law regulation.

- Never wait to begin mouth-to-mouth resuscitation if a manual resuscitator is not immediately available or cannot be used efficiently. (The efficiency of the ventilation should always be checked by watching the movement of patient chest and listening for the expiratory flow from the valve.)

- Do not override the pressure-limiting valve (for pop-off models only) to prevent excessive ventilation pressures that may cause lung rupture on patients. However, if medical assessment indicates the necessity of overriding the pressure-limiting valve, a manometer must be used to monitor ventiatory pressure and avoid the possibility of lung rupture.

- Remove obstruction from mask & valve by shaking the bag or rinse it with water.

- Store away from extremes of heat / cold and sunlight.

- Do not reuse this single use resuscitator to prevent cross infection or contamination.

2.Intended Use

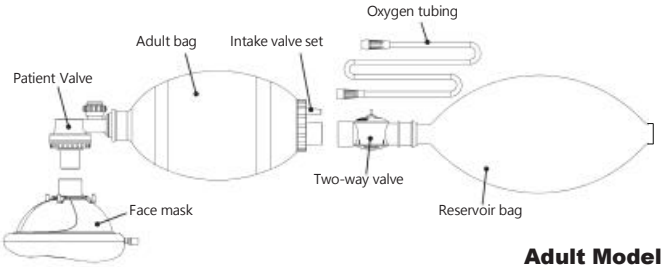
Manual resuscitator is a portable, manually operated device used in life emergency situations to provide lung ventilation (by means of pressing the compressible part of the device) to individual whose breathing is inadequate. It comes in adult, child and infant sizes as per patient's body mass range.

Adult bag

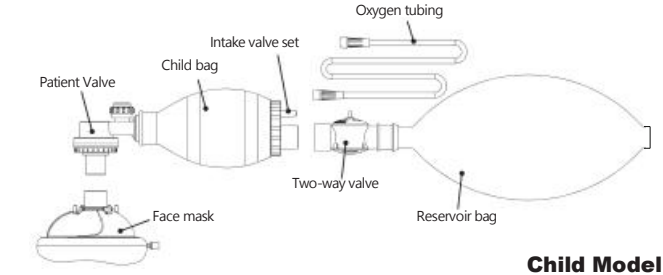
Child bag

Infant bag

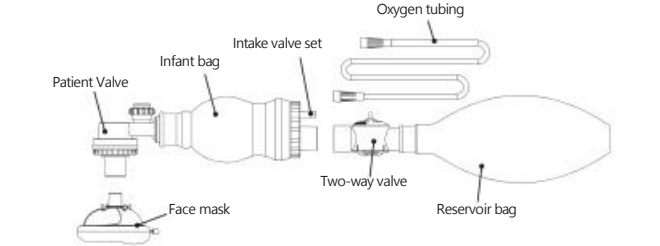
Adult bag : Recommended for adult/child with weight over 66 lbs (30 kgs)
Child bag : Recommended for child/infant with weight between 11-66 lbs (5-30 kgs)
Infant bag : Recommended for infant/neonate with weight below 11 lbs (5 kgs)



Adult Model



Child Model



Infant Model

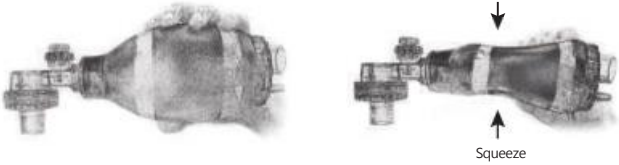
3.Direction for use

3.1 Function Test

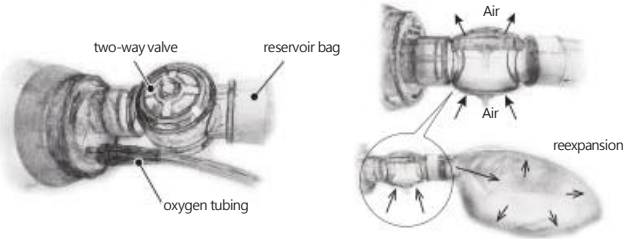
Make sure to conduct function tests:

- When first use a new resuscitator
- After new parts have been installed

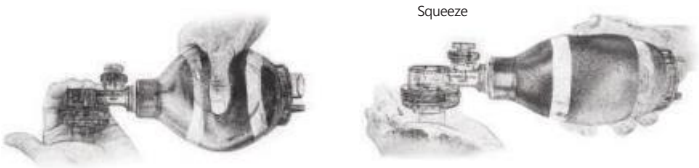
- Inspect the resuscitator to ensure all components are properly assembled, and there is no sign of wear or damage.



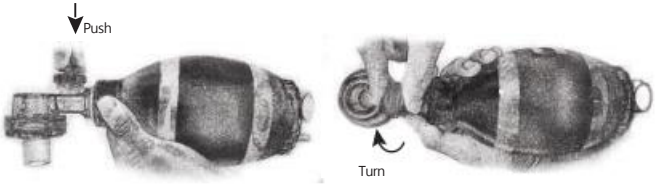
- Squeeze and release the bag several times, the bag should deflate and inflate immediately.



- Connect oxygen reservoir system, supply oxygen gas of no less than 15LPM for maximum oxygen storage and allow the reservoir fully extended. Or, perform several compression-release cycles on ventilation bag until the reservoir bag is flat & empty. Rapid reexpansion of the ventilation bag after flattening of reservoir bag confirms the reservoir valve efficiently lets in ambient air to compensate for lack of gas in the reservoir. If the reservoir fails to fill,check for the integrity of the two way valve or for a torn reservoir of blocked oxygen tubing.



Compress the ventilation bag with one hand and occlude its patient port with the other hand. Check for resistance by squeezing the bag.



Push and turn 90° the pop-off valve

Push and turn 90° the pop-off valve to unlock position-(applicable to with pressure limiting valve models only), compress the ventilation bag as mentioned above, there should be audible expiratory flow from the valve.

Replace a new resuscitator or component if the unit fails any of above tests.

3.2 Operating Instruction

Let patient lie down, open patient's mouth and clear obstruction from the airway. Do not push the forehead back to open airway as patient might have a potential neck or spinal injury.

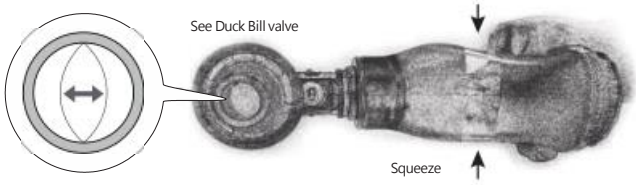
Lift the chin carefully. This will move the jaw forward and tilt the head backward allowing a path for air to travel to the lungs from the mouth and nose. If the airway stays blocked, tilt the head slowly and gently till the airway is open.

- Check for breathing by observing patient's chest rises and falls. If the patient is not breathing or not breathing normal, immediately start manual resuscitation with a resuscitator that passes function test.

- Cover patient's mouth and nose with mask. Clamp mask firmly to the face with index finger and thumb to achieve a tight seal. Before using a resuscitator, make sure to thoroughly train the correct application of the face mask.

- Ventilate the patient by rhythmically compressing the bag, allowing sufficient time between inspirations for patient's passive exhalation and bag re-expansion. Follow local guidelines for resuscitation.

- Check and make sure that the ventilation is properly functioning as per following procedure:
  - Observe rises and falls of the patient's chest.
  - Check patient's lip and face color through the transparent part of the mask.
  - Check the patient valve to determine if it is working properly through the transparent housing of the valve.
  - Check if the interior of the mask is being fogged during expiration.
  - Release the bag and listen to the expiratory flow from the patient valve
  - If the patient vomits during ventilation, clear patient's airway and squeeze the bag for a couple of times to assure no obstruction before resuming ventilation.



⚠ Note: Do not override the pressure-limiting valve (for with pop-off models only) to prevent excessive ventilation pressures that may cause lung rupture on patients. However, if medical assessment indicates the necessity of overriding the pressure-limiting valve, a manometer must be used to monitor ventilatory pressure and avoid the possibility of lung rupture.

3.3 Optional Accessories

Peep Valve PC (Disposable)
SR-S-A5(Child / Adult):
Adjustable from 2.5 to 20 cm/H2O
SR-S-A4 (Infant):
Adjustable from 1.5 to 10 cm/H^2O

Diverter
SR-S-A6
PC (Disposable)

Airway
SW-004~SW-011 (PE)
Or Guedel Airway SG-004~SG-011

Air Cushion Mask (PVC)
SM-060 ~ SM-065: With Valve
SM-060A ~SM-065A: No Valve
SM-260~SM-265: With Vertical Valve

For direction of use of these accessories, please refer to the respective user manuals.

3.4 Storage

The resuscitators and spare parts may be stored for a longer period of time. They must be inspected and tested at least once a month to ensure compliance with the function test described in this manual.

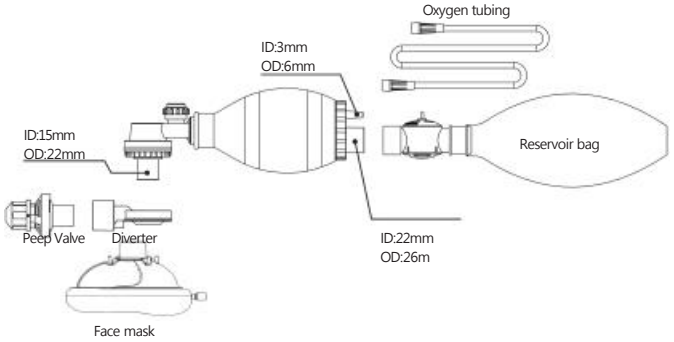
4.Specification

This resuscitator is in conformity with EN ISO 10651-4:2009 Lung ventilators-particular requirements for operator-powered resuscitators and Council Directive 93 / 42 /EEC-M5 / 2007 / 47 EC concerning Medical Devices.

Resuscitator	Adult(30 kgs+)	Child(5-30kgs)	Infant(5kgs-)
Bag volume (ml)	1800	550	320
Stroke volume (ml)	1060	320	140
Reservoir Bag (ml)	2700	2700	900
Pressure relief (optional)	60cm H^2O (or 40)	40 cm H^2O	
Expiratory/inspiratory resistance	2.0 cm H^2O / 4.0 cm H^2O		
Dead space	Less than 7.0 ml		
Operating Temperature	-18°C ~ 50°C test according to EN ISO 10651-4:2009		
Storage Temperature	15°C ~ 25°C		

Higher respiratory pressure can be obtained by overriding the pressure limiting device, use only if medical assessment indicates the necessarity.

Connections:



Delivered oxygen concentration (%) under various test conditions, values in parentheses () are various without an oxygen reservoir

Adult

Oxygen flow (L/min)	Tidal volume (ml) x Ventilation frequency					
	600x12	600x20	750x12	750x20	1000x12	1000x20
5	83 (32)	58 (34)	65 (34)	50 (30)	55 (31)	45 (31)
10	99 (37)	80 (38)	99 (37)	99 (36)	88 (36)	62 (36)
15	97 (46)	97 (45)	97 (46)	97 (44)	97 (44)	90 (46)

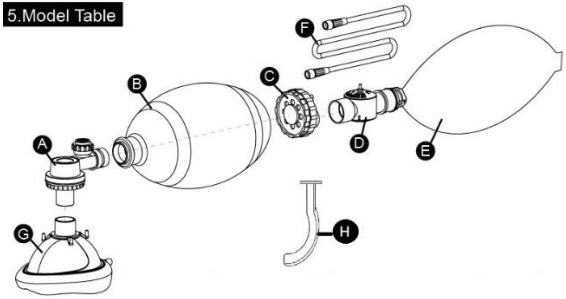
Child

Oxygen flow (L/min)	Tidal volume (ml) x Ventilation frequency		
	70x30	200x30	1000x12
5	83 (32)	65 (34)	55 (31)
10	99 (37)	99 (37)	88 (36)
15	97 (46)	97 (46)	97 (44)

Infant

Oxygen flow (L/min)	Tidal volume (ml) x Ventilation frequency			
	20x30	20x60	40x60	70x60
5	97 (75)	97 (72)	97 (59)	85 (52)
10	97 (75)	97 (78)	97 (78)	86 (61)
15	97 (95)	97 (92)	97 (82)	97 (73)

5.Model Table



No.	Part No.	Description	Material
A.	SR-011-S-14~23	Patient Valve Adult: 60 cm H^2O Child/Infant: 40 cm H^2O	PC / SILICONE / ST.ST.
B.	SR-011-S-12~13 SR-011-S-33~13 SR-011-S-34~13	Adult Resuscitator Bag Child Resuscitator Bag Infant Resuscitator Bag	PVC
C	SR-011-S-09~11	Intake Valve	PC / SILICONE
D	SR-011-S-01~07	Reservoir Two Way Valve	PC / SILICONE
E		Reservoir bag (1,700ml)	PE
F	SNB-030B-S-005	Oxygen Tubing(200 cm)	PVC
G.	SP-035 SP-033 SM-030	#5 PVC Mask #3 PVC Mask #0 Silicone Mask	PVC PVC SILICONE
H.	SW-004~SW-011	Airway	PE

6. Warranty

Dear Customer,
Thank you for purchasing this manual resuscitator. If your product needs warranty service, please contact our authorized distributor. To avoid any inconvenience on your part, we would suggest you reading the instruction for use carefully before contacting our distributor.
By this limited warranty, Sturdy warrants the manual resuscitator against defects in materials and workmanship for a period of one (1) year from original date of purchase. During the warranty period,we will repair or replace without charge for labor or parts with the defective products delivered by purchasers at their own discretion/ expense to the designated premises.

This warranty covers none of the following:

1. Scheduled maintenance and repair or replacement of parts due to normal wear and tear.
2. Damage resulting from improper maintenance, negligence, unskillful use.
3. Failure to use the product for its intended use or in accordance with Sturdy's instruction for use on the proper use and maintenance.
4. Compensation for direct or indirect damages of any kind to people or property due to product inefficiency.
5. Repair or alternation done by customer or any unauthorized third parties.
6. Accidents, fire, improper ventilation or any cause beyond the control of the manufacturer.

Product shelf life : 2 years from manufacture date

You are welcome to contact our distributor if you have any question about the product or warranty service.

OEM for Sturdy Industrial Co., Ltd.
Headstar Medical Products Co., Ltd.
9F, No.288, Sec. 2, New Taipei Blvd.,
Xinzhuang Dist., New Taipei City 242, Taiwan

EC REP
Obelis S.A.
Boulevard Général Wahis 53
1030 Brussels, Belgium

Made in Taiwan

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