[Product Name]
Manual Resuscitator

[Product Description]
The Manual Resuscitator consists of a Pressure Limitng Valve, an face mask, an oxygen tube, Resuscitation Bag, an One-way valve, a Reservoir Bag, a Mouth Opener, and a Guedel Airway.

[Intended Use]
It is used to provide lung ventilation for patients with sudden dyspnea or respiratory failure in cases of incomplete power supply and emergency.

[Intended User]
Professional medical staff

[Type(s)/Specification(s)]

Type	Specification	REF No.
PVC type	Adult	MRPA000
	Child	MRPC000
	Infant	IMRP000
Silicone type	Adult	MRSA000
	Child	MRSC000
	Infant	IMRS000

[Differences between different type and specification]

Parts name	Components	PVC type			Silicone type		
		Adult	Child	Infant	Adult	Child	Infant
Resuscitator	Pressure Limitng Valve	◆	◆	◆	◆	◆	◆
	Reservoir Bag	2000 ml +400ml -200ml	1600± 300ml	1600± 300ml	2000ml +400ml -200ml	1600± 300ml	1600± 300ml
	Resuscitation Bag	1700 ±100 ml	500±5 0ml	300±5 0ml	1700±1 00ml	500±5 0ml	300±5 0ml
	Inlet Valve	◆	◆	◆	◆	◆	◆
Face Mask		Soft shell type			Detachable type	Bending edge	Bending edge
		4#	2#	1#	5#	2#	1#
Oxygen Tube		◆	◆	◆	◆	◆	◆
Mouth Opener		◆	◆	◆	◆	◆	◆
Guedel Airway		Normal type			Transparent type		
		9	7	4	9	7	4
Note: ◆ Indicates that the specifications of the parts used are same.							

[Indication]
1) Cardiopulmonary resuscitation;
2) Respiratory depression caused by various types of poisoning;
3) Muscles of respiration paralysis caused by nerve and muscle diseases;
4) Respiratory depression caused by various electrolyte disorders;
5) Various large-scale surgeries;
6) Cooperate with oxygen therapy for thrombolytic therapy;
7) Transporting patients is suitable for special examinations of mechanically ventilated patients, entering and exiting the operating room, and other situations; Temporary replacement ventilator;
8) When encountering special situations such as obstruction or power outage of the ventilator, a Manual Resuscitator can be temporarily used to replace it.

[Contraindications]
1) Moderate or above active hemoptysis;
2) Acute myocardial infarction;
3) Tension pneumothorax and mediastinal emphysema without decompression and drainage;
4) Massive pleural effusion;
5) Asphyxiating Respiratory failure caused by serious mistakes;
6) Severe lung cysts, pulmonary bullae, etc.

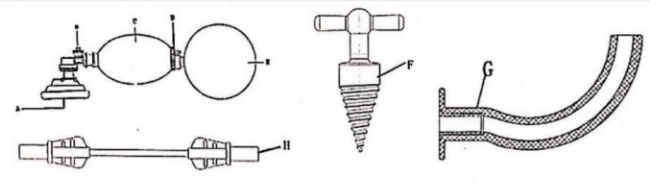
[Instructions for use]
1. Evaluation:
(1) Indications and indications of whether to use a Manual Resuscitator, such as acute respiratory failure, respiratory arrest or weak breathing that has not improved after active treatment, and pulmonary ventilation is obviously insufficient: chronic respiratory failure, no response after various treatments Improve or have pulmonary encephalopathy, before using the ventilator or when the ventilator is stopped;
(2) Assess whether there are contraindications to the use of Manual Resuscitators, such as moderately active hemoptysis, myocardial infarction, and large pleural effusions.
2. Under the condition of a compressed oxygen source, connect the face mask, Resuscitation Bag and oxygen, and adjust the oxygen flow rate to 6L/min-10L/min (oxygen supply concentration is 40%-60%) to fill the air storage bag. (Note: It is not necessary to connect the oxygen tube and the Reservoir Bag under the condition of no compressed oxygen source).
3. Open the airway, eliminate secretions and vomit in the upper respiratory tract, loosen the patient's collar, etc. The operator stands on the side of the patient's head, tilts the patient's head back, and lifts the lower jaw.
4. Put the face mask over the patient's mouth and nose, and press tightly to prevent air leakage. If the patient with tracheal intubation or tracheotomy uses a Manual Resuscitator, the sputum should be sucked up first, and the Resuscitation Bag should be inflated before use. When the Manual Resuscitator is in normal use, the safety pressure valve should be open and can be popped up. If it is necessary to use a gas with a pressure higher than the safety pressure valve, the safety pressure valve can be pressed and rotated to close it.
5. The method of squeezing the Resuscitation Bag with both hands: pinch the middle part of the Resuscitation Bag with both hands, with the two thumbs facing inward, and the four fingers close together or slightly separated, squeeze the Resuscitation Bag evenly with both hands, and start the next squeeze after the Resuscitation Bag re-expands Compress the breathing bulb as much as possible when the patient inhales.
6. Pay attention to tidal volume, respiratory rate, respiratory ratio, etc. when using.
(1) Generally, the tidal volume is 8-12ml/kg (usually the tidal volume of 400-600ml for adults is enough to make the chest wall swell), it is better to use ventilation, and when conditions permit, measure the partial pressure of carbon dioxide to adjust the ventilation volume and avoid hyperventilation .
(2) The respiratory rate is 12-16 times/min for adults, 14-20 times/min for children, and 20-40 times/min for infants. When you squeeze the Resuscitation Bag quickly, you should pay attention to the frequency of the Resuscitation Bag and the coordination of the patient's breathing. There should be sufficient time between the patient's exhalation and the balloon's inflation and reset to prevent

squeezing the balloon when the patient exhales.
(3) The breathing time ratio for adults is generally 1:1.5-2: for patients with COPD and respiratory distress syndrome, the frequency is 12-14 breaths/minute, the breath-to-expiration ratio is 1:2-3, and the tidal volume: the tidal volume is slightly few.
7. Observe and evaluate patients. During use, the patient's adaptability to the respirator should be closely observed. Chest and abdomen rise and fall, skin color, auscultation breath sounds, vital signs, and oxygen saturation readings.
8. The applicable range of body weight for each type of Manual Resuscitator is: 5kg< Infant≤10kg, 10kg<children≤40kg, adult>40kg.

[Warnings and Precautions]
1. This product is suitable for on-site rescue of patients with respiratory failure or sudden respiratory arrest.
2. The Manual Resuscitator consists of resuscitator, face mask, oxygen tube, mouth opener and guedel airway, and the final status of each component provided in the device are as follows:

Parts name	Components	Final supply status	
		PVC type	Silicone type
Resuscitator	Pressure Limitng Valve	non-sterile	non-sterile
	Reservoir Bag		
	Resuscitation Bag		
	Inlet Valve		
Face Mask		sterile	non-sterile
Oxygen Tube		non-sterile	non-sterile
Mouth Opener		sterile	sterile
Guedel Airway		sterile	sterile

All non-sterile components provided should be scrubbed with soapy water before use, rinsed with clean water, soaked with 1:400 disinfectant for 30 minutes, rinsed with cool water, dried, and assembled and tested according to Figure 1; Additionally, the resuscitator should be disassembled according to Figure 2 before cleaning.;
All sterile components provided shall be sterilized using EO, and shall be sterilized before leaving the factory. The packaging shall be opened directly for use.



A. Face Mask; B. Pressure Limitng Valve; C. Resuscitation Bag; D. Inlet Valve; E. Reservoir Bag; F. Mouth Opener ; G. Guedel Airway; H. Oxygen Tube

Figure 1:Manual Resuscitator diagram

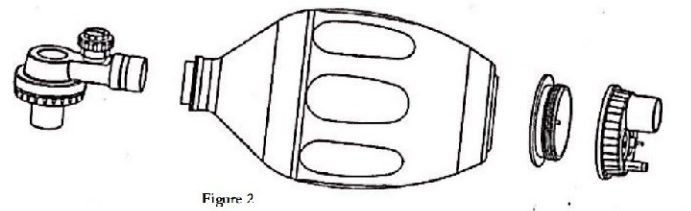


Figure 2

3. After the disposable parts are used, please according to the relevant regulations of the hospital or the local health department, have a qualified or invested institution conduct harmless disposal.
4. Before using the product, the medical staff should check the packaging of sterile parts (mouth opener, guedel airway, and face mask (soft shell type)), if the single package is damaged, do not use.

After that, check whether the patient connection port of the Resuscitation Bag is loose, If the patient's connection port is loose, the user should check whether it will affect the operation. If it does not affect the operation, it can be used normally; when using the product, if the patient does not show the corresponding thoracic lifting and falling symptoms, please try again. Check whether the patient's breathing cavity is unblocked, whether the product's intake valve, patient valve, Resuscitation Bag, and Face Mask are working normally, and whether all connections are unimpeded and leak-free. If effective ventilation cannot be obtained, immediately switch to mouth-to-mouth ventilation, which is insufficient, reduced or no airflow may cause brain damage in ventilated patients: The product should be harmlessly disposed of by a qualified or authorized institution in accordance with the relevant regulations of the hospital or local health and family planning authorities.
5. Once the aseptic package is opened, even if the product is not used, it must be destroyed. The destruction procedure is carried out by a qualified or authorized institution according to the relevant regulations of the hospital or the local health and family planning department.
6. The problem that is easy to occur when using a Manual Resuscitator is that the patient cannot get effective ventilation due to the leakage of the exhalation valve. So check, test, repair and maintain regularly.
7. When squeezing the Resuscitation Bag, the pressure should not be too high, about 1/3-2/3 of the Resuscitation Bag should be squeezed, and it should not be too large, sometimes fast, or slow, so as not to damage the lung tissue, cause the disorder of the respiratory center, and affect breathing function recovery.
8. When the patient is found to be breathing spontaneously, assistance should be given according to the patient's breathing action so as not to affect the patient's spontaneous breathing.
9. Do a good job of psychological care for conscious patients, explain the purpose and significance of using the respirator, relieve tension, make them actively cooperate, and guide the patient to "inhale..." and "exhale..." while squeezing the Resuscitation Bag. "
10. The Pressure Limitng Valve should be in an open and pop-up state during normal use. If you need to use gas with a pressure higher than the Pressure Limitng Valve, you can press down the Pressure Limitng Valve knob and rotate the Pressure Limitng Valve to lock it. The valve is closed.
11. The elastic Resuscitation Bag should not be squeezed and deformed, so as not to affect the elasticity.
12. Please strictly abide by the corresponding surgical procedures, illegal operation is prohibited, and it is only used by professionals.
13. Before use, you must understand the method and function of the product in detail to ensure safe and effective use; please read this manual carefully before using the product. Insufficient ventilation, reduced or no airflow may result in patients receiving ventilation due to improper use without following the manual. Damage to the brain, or high ventilation pressures with the Pressure Limitng Valve closed can cause lung rupture in some patients.
14. The Manual Resuscitator can only inhale air and air-oxygen mixture breath, and it is forbidden to enter other breath or medicine that has not been clinically proven.
15. If the patient valve of the Manual Resuscitator is contaminated by the patient's vomit or blood during use, please suspend use first, and quickly press the Resuscitation Bag several times to blow out the dirt; if there are still residues, wash them with clean water and squeeze them hard quickly Press the Resuscitation Bag to dry it: if the dirt cannot be cleaned, discard it and replace it with a new Manual Resuscitator.
16. When it is necessary to connect the oxygen source, it should be kept away from the fire source. When using oil or grease, it should

not be close to the oxygen equipment. Do not smoke or use an open flame when using oxygen, as this may cause a fire.
17. Do not use it in a toxic environment. Harmful substances in this environment will be inhaled into the Manual Resuscitator and eventually cause harm to the patient.
18. All components of Manual Resuscitator are disposable products and cannot be re-sterilized, re-disinfected, or reused. If reusing may cause cross infection.

【Other matters】

1. Functional testing after reassembly and before use:
1) Manual Resuscitator: Lock the Pressure Limitng Valve to close the valve core, and cover the patient's connection port with your thumb, gently and quickly squeezing the Resuscitation Bag; Manual Resuscitators should be able to withstand compression; By loosening the Pressure Limitng Valve core to open the Pressure Limitng Valve, the Pressure Limitng Valve should be activated and the exhalation flow rate can be heard from the valve. Squeeze and release the Resuscitation Bag several times to ensure that air is discharged through the Pressure Limitng Valve; After removing the finger, gently and quickly squeeze the Resuscitation Bag, and air should be discharged from the patient's connector.
Attention: During functional testing or exhaust process, the valve plate may make a slight sound due to movement, but this will not affect the function of the Manual Resuscitator
2) Reservoir Bag: Provide a 5L/min airflow for the Reservoir Bag, check if the Reservoir Bag is full; if not, check the integrity of the two intake valves and whether the Reservoir Bag is damaged.
3) Oxygen Tube, approximately 200cm, provide a 10L/min airflow to the Oxygen Tube, check if oxygen is discharged from the end of the Oxygen Tube, and if not, check if the Oxygen Tube is blocked.
2. Resuscitation Bag size (long × Diameter: About 212mm for adults × 131mm, approximately 146mm for children × 100mm newborn approximately 122mm × 75mm
3. The weight of the packaging box (including the product) is approximately 0.9kg for adults, 0.64kg for children, and 0.58kg for Infant

[Attention]
Any serious incident that has occurred in relation to the device should be reported to the Henan Tuoren Medical Device Co.,Ltd. and the competent authority of the Member State in which the user and/or patient is established.

[Shelf-life]
Five years

[Sterilization Method]
All components provided in a sterile state shall be sterilized with EO, and shall be sterilized before leaving the factory.

[Storage and Transport Conditions]
1. Do not apply heavy pressure, direct sunlight, or rain or snow to avoid damaging the equipment;
2. During the transportation process, it should be handled with care and avoid severe collisions;
3. Keep away from ignition and heat sources to avoid severe collision of equipment;
4. Store in a cool and dry place, with good ventilation, no corrosive gases, and a relative humidity of no more than 80% indoors.

[Operating conditions]
Operating temperature: -18 ℃~50 ℃, operating humidity: 15%~95%

[Production Date]
See on the package.

[Symbol Explanation]

	Manufacturer		Do not re-use
LOT	Batch code		Use-by date
CN	Date of manufacture, Country of manufacture	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use	EC REP	Authorized representative in the European Community/ European Union
STERILE EO	Sterilized using ethylene oxide		Do not resterilize
	Consult instructions for use or consult electronic instructions for use	UDI	Unique device identifier
	Single sterile barrier system	MD	Medical device
	Keep away from sunlight		Keep dry
	Caution	CE 2862	CE Marking
	Stacking layer limit		Fragile, handle with care
30%	Humidity limitation	LATEX	Latex Free

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