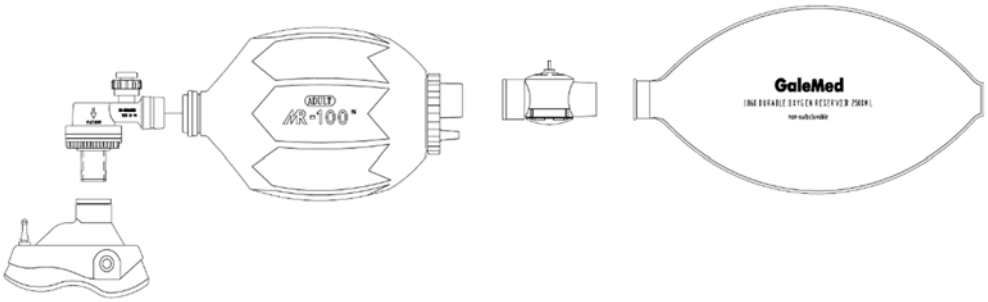
GaleMed

MR-100™ Resuscitator

MR-100 Resuscitator, Adult

AR0001 (1068)



Instruction for Use (IFU)

2. Version History

Version #	Document No	Change	Date
1			2020/11/18

3. Product Description

3.1 Intended Medical Use

3.1.1 Product name

Resuscitator

3.1.2 Intended Use

Provide or assist ventilation in patients whose breathing is inadequate.

3.1.3 Indications

The different models are indicated for different people according to their weight.

3.1.4 Contraindications

1. Adult resuscitator

No existing contraindications for using resuscitator to adult people.

2. Child resuscitator

No existing contraindications for using resuscitator to child people.

3. Infant resuscitator

a) Meconium-stained baby depressed at birth

b) Congenital diaphragmatic hernia

3.1.5 Patient Group

The adult resuscitator is for people with a body weight of more than 30 kg (66 lbs.)

The child resuscitator is for children with a body weight between 7 and 30 kg (15-66 lbs.)

The infant resuscitator is for infants with a body weight up to 7 kg (15 lbs.)

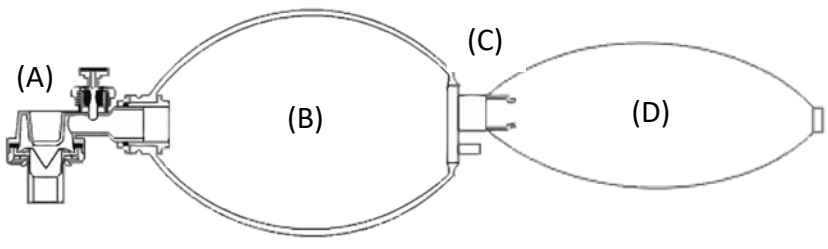
3.1.6 Intended User

This product is intended for use by qualified medical or emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques.

3.1.7 Principles of Operation

Assembly view of an artificial respiration system (A)

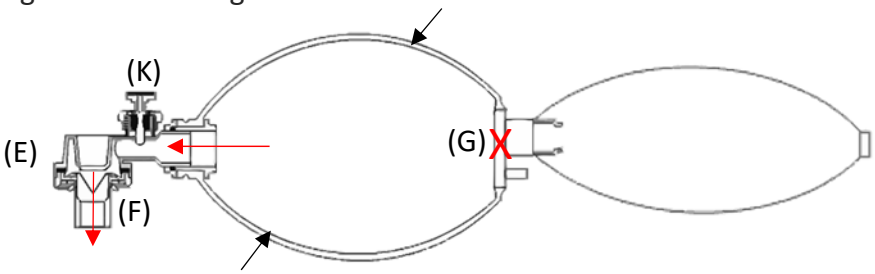
(A) Non-rebreathing (duckbill) Valve (B) Compressed Bag (C) All in 1 intake valve (D) Oxygen Reservoir. The Oxygen Reservoir may be removed if supplemental oxygen is not to be supplied.

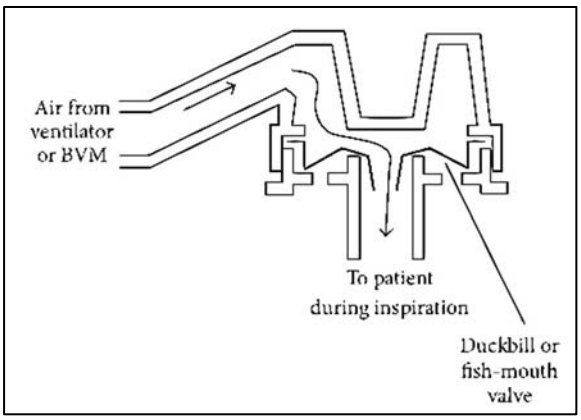


Assembly View (A)

Principle Drawing (B) – Inspiration

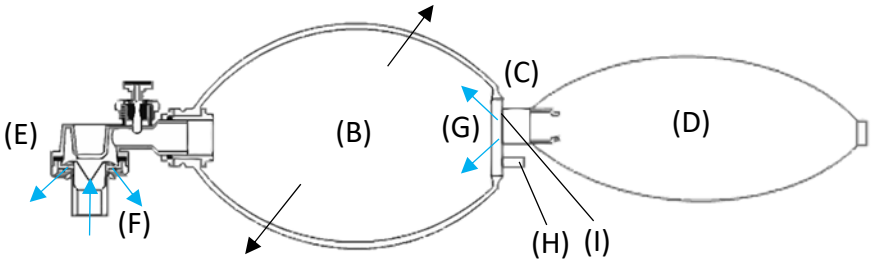
When compressing down the Resuscitator, it create the positive pressure and close the Intake Valve (G), the air inside the bag pushes the Duckbill Valve (E) downward, and block the expiration port (F), and deliver the air into the Silicone Bag then to the patient through the center of the Duckbill Valve, if the Oxygen is in use, it should be connected by (H) part, then the Oxygen will fill up the Reservoir through the Reservoir Valve, and installs in the Silicone Bag through the recovery inhale motion, then send directly into the patient's body by compressing the silicone bag.

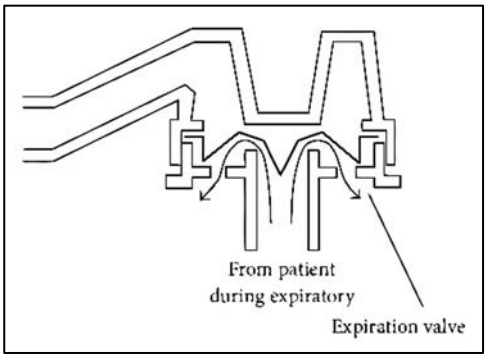




Principle Drawing (C) – Exhalation

When releasing the Silicone Bag (B), push upward the Duckbill Valve and keep it in close position, so to release the exhale air through the Exhale Valve (F).

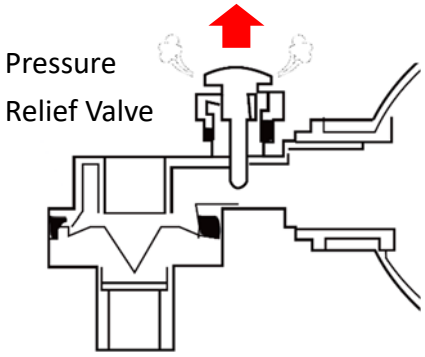




At the same time, the Inhale Valve (G) is opened by the expiratory pressure created by releasing the bag, and send the air into the bag through the top of the Reservoir Valve, and at the same time, send the Oxygen into the bag from the Oxygen Reservoir till the bag returns to the original shape before compressing. To avoid excessive Oxygen flow rate and low compressing frequency causing too high pressure inside the bag and the Reservoir, the Reservoir Valve (I) is specially designed to release the excessive air, to keep a low-rate Oxygen supply and ensure the patient's safety

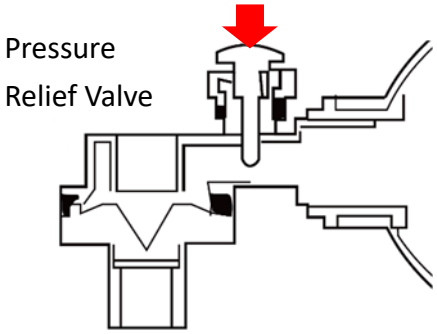
Principle Drawing (D)

GaleMed reusable resuscitators are equipped with pressure relief valves (optional), automatically provide and adjust the pressure in the lung, and keep it within 40 / 60 cmH_2O, any pressure exceed this standard will cause the pressure relief valve to jump off and push the pressure out to ensure the patient's safety.



Pressure Relief Valve Motion

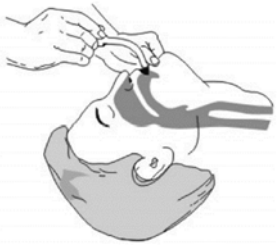
Should higher inspiratory pressure be required the pressure relief valve may be overridden by placing the thumb ever the valve as show as follows.



Overriding the Pressure Relief Valve

3.1.8 Direction for Use:

3.1.8.1 Reusable-Resuscitator Operation



1. Place the patient on back, pull his chin upward as possible to keep the airway and the mouth cavity in alliance line, so the patient can breathe smoothly.

2. Clean all visible foreign material inside the mouth and the throat.

3. Insert the oropharyngeal tube, keep the patient's mouth open to prevent tongue from occluding the airway. (Can use a mouth opener to open his mouth) The oropharyngeal tube can be selected according to the patient's mouth cavity size.

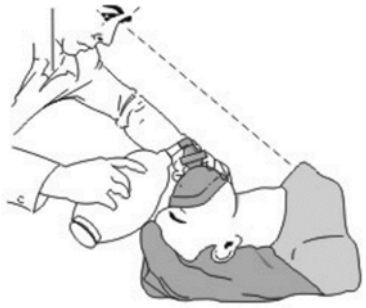
4. The emergency personnel should stay behind the patient's head, extend the head back and pull his chin upwards and towards the emergency personnel.

⚠ **Remark:** If the patient already has an airway inner tube inserted, or has been through an airway excise resect operation, then please remove the mask, connect the Non-rebreathing Valve connector with the airway inner tube, then following the standard operating instruction.

5. Cover the patient's mouth and nose with the mask, and press palm against the mask to keep it close to the patient's face.

6. Use the other hand to press on the Resuscitator, regularly compress sending with sufficient inhale/exhale frequency. (Adult: 12-16 times, Child: 14-20 times, Infant: 35-40 times)

7. The emergency personnel should check: to ensure that the patient is ventilating properly.



- Observe rise and fall of the patient's chest (accordingly with the pressing on the Resuscitator).
- Check the patients lips and face color through the transparent part of the mask.
- Check that the patient valve is working properly through the transparent housing.
- During exhalation, check that the interior of the mask is

- Testing the Resuscitator

GaleMed reusable resuscitator should be tested as follows:

• When first using the new Resuscitator
• (After cleaning and sterilizing)
• After any new parts have been fitted
• Monthly, if the Resuscitator is not frequently used. Equipment required: Test lung, 0-100 cmH2O manometer (for Infant and Child resuscitators only), flow meter, regulated gas supply, gas supply tubing.

3.1.8.2 PEEP valve Operation

1. Fit the Flow Diverter over the downstream housing on the resuscitator as shown in the illustration. Be sure the diverter is fully seated.
2. Position the Flow Diverter as desired to direct exhaled gases away from the rescuer and/or patient.
3. Squeeze the resuscitator bag several times to assure that the unit is functioning properly.
4. Select the Peep Valve with appropriate range (2 -10cm H_2O or 5-20cm H_2O)

5. Set the Peep Valve knob to the approximate value shown on the Peep Valve housing.
6. Connect the Peep Valve to the Flow Diverter port as shown in the illustration. Connect the resuscitator to a manometer and test lung. Ventilate the test lung and adjust the Peep Valve as required to obtain the desired end expiratory pressure.
7. Ventilate the patient following ACLS procedures for ventilation. Watch the chest rise during ventilation. Also, during ventilation, periodically check for:
- signs of cyanosis;
- adequacy of ventilation;
- proper airway pressure;
- secure connection of Peep valve and diverter.
8. Between patient use or periodically, clean and sterilize the Peep Valve and Flow Diverter.
- Testing the Resuscitator

3.2 System Overview

3.2.1 Intended for use together with other devices:
Oxygen Tubing, Airway, Silicone Mask, Aircushion Mask, PEEP Valve, Disposable manometer

3.3 Specification/Functions

3.3.1 Operating Environmental Temperature Limits:
-18°C to +50°C
3.3.2 Storage Environmental Temperature Limits:
-40°C to 60°C (-104°F to 140°F)
3.3.3 Range of setting:

	Adult Resuscitator	Child Resuscitator	Infant Resuscitator
Valve resistance	<4.0 cmH_2O		
Oxygen concentration	>95% @15 LPM		
Bag capacity (ml)	1500	550	280
Max delivered volume (ml)	1350	350	160
Safety pressure-relief valve	60±10 cmH_2O	40±5 cmH_2O	40±5 cmH_2O
Reservoir bag (ml)	2000	1000	500
Mask size	#4	#3	#0

Durable PEEP Valve

REF	SAP REF	Product name	Pressure range	Connector size	Package
2403	AV0035	Durable PEEP Valve	2-10cmH2O	30F (Orange)	1 pc/pkg, 50 pcs/box
2413	AV0037	Durable PEEP Valve	5~20cmH2O	30F	1 pc/pkg, 50 pcs/box
2001	AR0003	Durable PEEP Valve Diverter	-	30/26mm	1 pc/pkg, 50 pcs/box

Disposable Manometer

REF	SAP REF	Description	Specification
4524	AP0006	Pressure manometer, 0~60cmH2O	0-60cmH_2O
4526	AP0007	Pressure manometer, 0~30cmH2O	0-30 cmH_2O
4527	AP0002	Pressure manometer, 0~20cmH2O	0-20 cmH_2O

3.3.4 Connectors:

- Patient valves: 22/15mm
- O_2 inlet: 6M
- Oxygen reservoir bag connector: 22M
- Oxygen reservoir bag: 22F
- optional diverter: 30M

3.3.5 Material list:

PARTS	***MATERIAL***
Face masks	Silicone /PSF
Flexible valve parts	Silicone
Compression bags	Silicone
Transparent valve parts	PSF
O_2 tubing	PVC
Oxygen Reservoir Bag	Silicone & PSF
PEEP valve all hard plastic	Polysulfone
PEEP valve and grommet	Silicone
PEEP valve spring, screw and shafter.	Stainless steel

4. General Safety Instruction

4.1 Operating Condition

4.1.1 Care during shipping and storage

- For compact storage, e.g., in an emergency case, the inlet end can be pushed halfway into the bag.
- Never store the resuscitator in a compressed or folded state.
- Never excessively squeeze the bag during storage. When the resuscitator is ready for use it should not be kept in direct sunlight or in a heated environment.
- Storage temperature: -40°C to 60°C (-104°F to 140°F)
- For long-term storage or transportation, the resuscitator should be kept in closed packing in a cool place away from direct sunlight.

4.2 Possible side-effect

Compressed pressure can increase in transpulmonary pressure, the patient's blood pressure can be reduced due to a reduction in pre-load.

4.3 Possible Risks

4.3.1 Residual Risk

0. Hyperventilation may be occurred by three factors: there is no monitoring of ventilatory parameters on manual resuscitators, there is no direct evaluation of ventilation quality, and there is limited understanding of the patient's needs from rescuers with less experience.
1. High pressure can cause barotrauma (injury from high pressure), especially for neonates and prefer to use a BVM with an integrated manometer.
2. High inspiratory lung volumes (or pressures) can cause injury through alveolar overdistension, causing alveolar rupture, and cell death.
3. Extra pressure or volume can cause gastric insufflation, creating a greater risk of aspiration on certain patient.

4.3.2 Procedure to avoid

1. Always keep peak airway pressure below 30cmH_2O and tidal volume are based on predicted body weight, not actual body weight.
2. Limit the tidal volume by choosing suitable compressed bag.

4.4 Warning/Precaution

A Warning states a condition, hazard, or unsafe practice that can result in serious personal injury or death.
A Precaution states a condition, hazard, or unsafe practice that can result in minor personal injury or damage to the manikin.

Precautions

• precaution: Federal law (US) restricts this device to sale by or on the order of a physician.

• The GaleMed reusable resuscitator should only be used by persons who have received adequate training in the use of resuscitators.

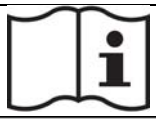
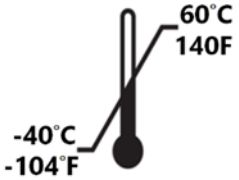
• Resuscitators should not be used with supplemental oxygen where smoking is permitted or when fire, flame, oil or grease is in close proximity.

• Resuscitators should not be used in toxic or hazardous atmospheres.

• The use of third-party products and oxygen delivery devices (e.g. filters and demand valves) with the GaleMed reusable resuscitator may have an effect on performance. Please consult with the manufacturer of the third-party device to verify compatibility with the GaleMed reusable resuscitator and obtain information on possible GaleMed reusable resuscitator performance changes.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

6. Symbol glossary

Symbol	Description
	CE mark
	Caution
	Consult instructions for use
	Do not use if package is damaged
	Use-by date
	Batch code
	Temperature Limit
	Authorized Representative in the European Community
	Manufacturer
	Catalog number

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