HSINER®

MD LATEX

Resuscitator and Accessories-Manual Resuscitator

Adult

REF **60347**

LOT

Date of Manufacture: YYYY-MM

Use by: YYYY-MM

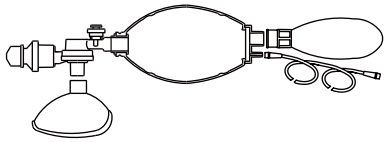
Read instruction manual carefully before use on a patient

· This resuscitator was intended to use on a adult with a minimum body weight of 20 kg

Item	Material	Specification
Patient valve	PSF, Silicone	W / POP-OFF valve 60 cmH_2O
Peep valve	PSF, Silicone	5~20cmH_2O
Bag	Silcone	1500 ml
All in one intake valve	PSF, Silicone	
Reservoir bag	Silicone, PSF	2000 ml
Mask	Silicone	Mode 10115
Oxygen tube	PVC	Model 30200

Features:

*Storage temperature: 15ºC ~ 25ºC
*Inspiratory resistance: ≤5 cmH_2O @ 50 LPM
*Expiratory resistance : ≤5 cmH_2O @ 50 LPM
*Peep valve: 5~20 cmH_2O
*POP-OFF valve: Gas release when Pressure ≤60 cmH_2O@60LPM
*Deadspace: <6ml
*Expected Delivery Volume: up to 675 ml
*Product Dimension (assembled): 630 mm (L)*140 mm (W)*150 mm (H)
*Mass: <500 grams



⚠ Warning and cautions:

* Intended for use by qualified trained personnel.
* Test the product functions prior to use on a patient / after reassembly.
* Do not use the product in toxic atmosphere.
* Do not use oil, grease or any hydrocarbon based substance on any part of the products,Avoid possible ignition during operation.
* Do not disassemble the POP-OFF valve.
* For best performance of this product, please use within 5 years from the date of manufacture.
* The device must be Disinfection/Sterlization before reuse, follow the Disinfection / Sterilization procedure.
* Do not disinfect or sterile PVC material components (reservoir bag, oxygen tubing, airways if applicable).
* Visually inspect and test valve functions to ensure proper operation of the manual resuscitator prior to patient use. Improper assembly of the flap valves, intake membrane disk membrane and duckbill valve may affect performance.
* If any breakage found by visual check, please do not use the resuscitator, and replace with another.

Instruction for use:

1.Pull out the resuscitator from both side with hand.
2.Assemble the patient valve, reservoir bag and resuscitator properly.
3.Connect the mask and PEEP valve onto patient valve.
4.Make sure the POP-OFF valve is unlocked by twisting and pulling the lock button; test its function by blocking the patient valve and squeezing the bag, and observe if air can leak from the POP-OFF valve.
5.Connect the oxygen tube to a regulated oxygen source.
6.Adjust the oxygen flow so that reservoir expands completely during inspiration and nearly collapses as the squeeze bag refills during exhalation.
7.Prior to connecting to a patient, check the function of resuscitator and make sure all connections are proper position. Observe the intake valve, reservoir bag and patient valve be allowing all phases of the ventilation without any leakage.
8.Pull and test valve to check if getting stick, test function to check if it's in good performance.
9.Put the mask onto patient's face to cover the nose and jaw.
10.Press thumb and forefinger on the mask, check by the other hand to make sure the mask has been attached to patient's face properly.
11.Squeeze the bag to deliver a breath, observe the patient's chest wall rise to confirm inspiration.
12.Release the bag to allow patient exhalation, observe the chest wall fall to confirm exhalation.
13.If any contamination pollute the bag during operation, clean the contaminant immediately.

Function Testing

Test valve functions to ensure proper operation of the resuscitator after each disassembly- reassembly. An O2 Reservoir Bag is needed to complete the test procedures described below:

1.0 Intake/Reservoir Valve

a) Compress the ventilation bag with one hand and close its neck opening with your other hand. Release the grip on the bag. Rapid bag re-expansion confirms efficient air intake.

b) Close the neck opening and try to compress the bag. If the bag cannot be compressed with reasonable force, or if bag compression forces the air out between your hand and neck of the bag, the valve efficiently prevents backward leakage of air.

2.1 Patient Valve

a) Assure that a (single) Duckbill Valve has been installed in the Patient Valve. Attach the Patient Valve to the bag. Hold a Reservoir Bag over the patient port connector pressing with your thumb on the reservoir bag connector.
Ensure tight seal between the patient port and Reservoir Bag.
Compress the bag with your other hand several times. Inspect that the Lip Valve opens during compression.
Filling of the Reservoir Bag in this set-up confirms that the Patient Valve efficiently directs air to the patient.

b) With the filled Reservoir Bag held firmly to the valve connector, compress the Reservoir Bag while watching the external Disk Membrane. Lifting of the Disk Membrane from its seat confirms that air is correctly directed to atmosphere instead of being returned to the ventilation bag.

2.2 Patient Valve with Pressure Relief Valve

Close patient port connector with your thumb while compressing the bag several times. Visual and audible opening of the relief valve confirms its operation.
Function Testing

3.0 Reservoir Flap Valves

(located in the Intake Valve assembly.)

a) Do as described and shown in 2.1a above in order to fill the Reservoir Bag with ambient air. Attach reservoir to the Intake Valve and press on Reservoir Bag.
Compression of the Reservoir Bag and visual rise of the outlet Flap Valve confirms that the Reservoir Valve efficiently vents excessive gas to atmosphere.

b) Do as described and shown in 2.1a above in order to fill a Reservoir Bag with ambient air. Attach reservoir to the Intake Valve. With the Patient Valve in place and the reservoir attached to the Intake Valve, perform several compression-release cycles on the ventilation bag until the Reservoir Bag is flat and empty.Rapid re-expansion of the ventilation bag after flattening of the Reservoir Bag confirms that the Reservoir Valve efficiently lets in ambient air.

Procedure for removal of contaminants:

If the patient valve is contaminated with vomit, or secretions during ventilation, please disconnect the device and clear the valve as follows:

a. Disassembly the contaminated part.
b. Rapidly compress the squeeze bag to deliver several sharp breaths to expel the contaminant.
c. Rinse the patient valve in water and then rapidly compress the squeeze bag to deliver several breaths to expel the contaminant.
d. If the contaminant still does not clear, discard this resuscitator.

Disinfection / Sterilization Notice

Chemical:2% Glutaraldehyde for 20min
Autoclave: up to 134ºC for 10min

Oxygen Flow Rate	*Percent Oxygen Delivered*
Resuscitator Patient Category	DUT Adult
2 l/m	50%
4 l/m	74%
6 l/m	96%
8 l/m	98%
10 l/m	99%
15 l/m	99%
All with oxygen reservoir bag in place	

Manufactured by
HSINER Co.,Ltd.
312, Jhongshan Rd., Shengang Dist,
Taichung City 429, Taiwan
Tel: 886-4-25152480 Fax: 886-4-25152482
Email:sales@hsiner.com
Web Site:http://www.hsiner.com

EC REP EU Representative
mdi Europa GmbH
Langenhagener Str. 71,
D-30855 Langenhagen
Tel: +49 511 3908 9530
Fax: +49 511 3908 9539
http://www.mdi-europa.com

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Disinfection & Sterilization Procedure of Reusable Manual Resuscitator

This following disinfection and sterilization methods are intended for reuse of the resuscitator in hospital environment. These methods are the recommended procedures, and we advise that each healthcare facility consult its own procedures before carrying out the following instructions.

Sterilization Occasion:

- Between patients.
- Whenever the resuscitator becomes contaminated.
- Every 24 hours continuous of use with the same patient.

Procedure:

1. Disassemble the Resuscitator parts, such as mask, oxygen tube, PEEP valve and reservoir bag set etc.
2. Discard the parts which were not made of silicone or PSF materials, such as oxygen tube, PVC/PE reservoir bag, PC/PVC mask etc.
   *Please see the specification table in the instructions for uses.
3. Rinse all reusable parts in clean water to remove residue.
4. Hands wash all parts of the resuscitator thoroughly with neutral cleaning detergent about 5 minutes.
5. Rinse all reusable parts in clean water to remove remaining detergent and let the parts air dry.
6. Disinfecting/Sterilization:
   - Disinfecting: Soak parts in Cidex 2% Glutaraldehyde disinfection for 20 min: Consult disinfectant supplier before first use. Rinse thoroughly with sterile water; or
   - Sterilization: Autoclaving not to exceed 134ºC for 10 min.

7. Dry them thoroughly. Inspect all components to confirm that they are clean and dry. If parts are worn or damaged, discard them.
8. Replace discarded parts, such as described in procedure 2 and 7, with new parts before assembling.
9. Follow the function check procedure for all valves after assembling.
   *Please see the procedure of Function Testing in the instructions for uses.

Note:

- The dispose of resuscitator parts should follow the local laws related to hospitals wastes.

- The overall main parts of the silicone resuscitator's maximum reprocessing cycles are recommended as 30 times (verified for chemical and autoclave), if any part found breakage or malfunction after reprocessing, should replace the part with new, or replace the whole manual resuscitator.

- HSINER cannot give any assurance that any deviations from the procedures listed as above, because of the deviations might cause the performance to become unacceptable.