

Pocket BVM Operating Instructions: Additional copies are available from MicroBVM on request

The Pocket BVM is manufactured by MicroBVM Systems Ltd.

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Table of Contents:

2

| Intended Use: | |
|-----------------|--|
| WARNINGS: | |
| PRECAUTIONS: | |
| Pocket BVM Use: | |
| Specifications: | |
| | |

Adult single patient use resuscitator including face mask reservoir bag and oxygen inlet.

Intended Use:

The Pocket BVM Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support of adult patients.

The Pocket BVM is a single-patient-use device and, as such, no service is required. It should not be re-used on other patients.

The Pocket BVM is not sterile.

The Pocket BVM is to be used by trained personnel only.

U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

WARNINGS:

- Warning: Oil or grease should not be used in close proximity to oxygen . equipment - fire may result.
- Warning: Do not smoke or use open flames when oxygen is in use fire may result.
- Warning: Reduced or insufficient airflow may result in brain damage to the patient being ventilated.

Warning: Improper function could lead to inadequate ventilation, resulting in serious injury or death.

3

- Warning: If efficient ventilation cannot be obtained with this device. the operator should immediately switch to mouth-to-mouth and/or mouthto-nose resuscitation.
- Warning: Use in contaminated environments can be hazardous unless entrainment of contaminants is prevented. Warning: Oxygen flow should not exceed 35 L/min. .

PRECAUTIONS:

- Caution: Only persons with adequate training should use the Pocket . BVM .
- Caution: Users of this product must be familiar with the important information in the directions for use.
- Caution: Test each unit prior to use.
- Caution: This product is intended for single use only. Do not attempt to clean, decontaminate or sterilize.
- Caution: Do not use the resuscitator in toxic or hazardous atmosphere, as silicone rubber is highly permeable to gasses. Caution: Never store the resuscitator in a squeezed or compressed
- state, other than folded at the folding zones in the original packaging. Permanent deformation of the bag will occur, which may reduce the ventilation efficiency.
- Caution: Avoid contamination with oil and grease. Such products may affect the integrity of the resuscitator materials. **Caution:** Oil or grease should not be used in proximity to the resuscitator
- fire may result.
- Caution: There is danger from smoking or open flames in the presence of high oxygen concentrations.

Pocket BVM Use:

1. Unpack and assemble the Pocket BVM from the protective carrying case (as illustrated in Figure 1). 2. Briefly test the Pocket BVM for correct function. 3. Ventilate the patient.

5

1. Unpack and Assemble the Pocket BVM:



Figure 1 – Unpacking the Pocket BVM

- Separate the Face Mask from the folded Resuscitator Bag. Fully expand the Resuscitator Bag from its folded position by pulling both end valves (Front patient valve housing (air/O₂ exit port) and rear air/O2 inlet valve) outwards (in opposite directions) while twisting the Patient Valve.
- Caution: Do not pull the O2 Reservoir Bag. Do not pull valve. Tearing may occur.
- Attach the Face Mask to the Patient Valve housing.
- 2. Functional Test for the Pocket BVM, prior to use:

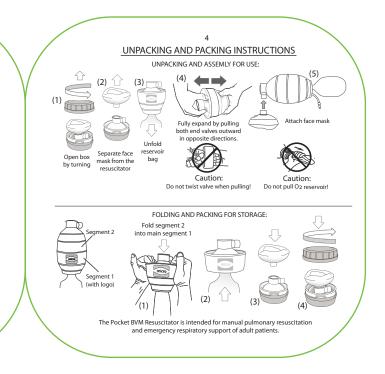
- Check the resuscitator by squeezing a few times to confirm that the Inlet Valve and Patient Valve are both functioning, i.e., that air is entering into the squeeze bag and exiting from the patient valve.
- · Check that the bag fills. This is confirmed by visible expansion and relaxation of the
- Using your thumb, block the Patient Port, squeeze the bag and hold for positive pressure, to verify that the system is leak free.
- If there is air leak from the patient valve, tighten the Expiratory connector and try gain. If any of the components (such as the valves) are not fully functional, do not use this
- device

3. Ventilate the patient:

- If resuscitating with Oxygen, attach the oxygen supply tube to a regulated oxygen source and set desired flow. Note: O2 should be administered as soon as possible.
- Use the recommended techniques to position the patient correctly, to open and clear the mouth and airways, and to hold the mask firmly against the face.
- Ensure that the facemask forms an adequate seal with the patient's face. A tight seal
- between face and mask is essential. Failure to attain a tight seal may result in reduced or no ventilation.
- The Pocket BVM functions must be visible and audible: Listen for expiratory airflow from the valves.
- · Ventilate the patient: During insufflation observe the rise of the patient's chest. Release the bag abruptly, listen for the expiratory flow from the patient valve and observe the lowering of the chest. If continued resistance to insufflation is encountered, check for airway obstruction, or correct the backward head tilt.
- If the patient vomits during mask ventilation, immediately clear the patient's airways of vomitus using recommended techniques.
- Clear the Pocket BVM of vomitus, and freely compress the bag a few times before resuming ventilation.
- The correct ventilation frequency may vary: Please follow the current ventilation frequency recommended by gional, national or international guidelines.

Specifications:

| The body mass range for which the resuscitator is | >40 kg (88 lbs.) |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| suitable for use Operating environmental limits | -18 °C (0 °F) to |
| Storage environmental limits | <u>50 °C (122 °F)</u> -40° C (-40 °F) to + 60° C (140 °F) |
| Substances, other than air, which can be administered by the resuscitator | Oxygen |
| Delivered oxygen concentrations under various test conditions | 55% (at 2 L/min) to 100% (at 8 L/min) |
| Gas inlet tube connection | 15mm length x 6mm O.D. |
| Stroke-volume range for operator-powered resuscitators | 800 ml |
| Apparatus dead space (backward leakage and forward leakage where appropriate) | <6 ml |
| Expiratory resistance | 3.4 cm H ₂ O |
| Inspiratory resistance | -4.5 cm H ₂ O |
| The end-expiratory pressure generated by the resuscitator in normal use, if greater than 0,2 kPa (2 cmH ₂ 0); | (<0,2 kPa) |
| External dimensions of the resuscitator | 217 mm (length) x 121 mm (diameter) |
| External dimensions of resuscitator in case | 63 mm (height) x 134 mm (diameter) |
| Mass of the resuscitator, face mask and the resuscitator case. | Resuscitator 273 g Case. 90 g, Mask 87 g, Total 450 g |
| | |



EC REP

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Explanation of symbols:

- Manufacturer EC REP - European Authorized Representative. LOT - Lot Number - Year of manufacture of active devices 4 - Limit temperature

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