SINGLE PATIENT USE ONLY

## INFANT BAGEASY SPECIFICATIONS

| | |
|---|---|
| Applicable Patient Size: | <7 kg (<15 ½ lbs) |
| O2 Concentrations* at 20° C: | >93% at 10 L/min $O_2$ flow; typical values of 97% to 99% *Tested per ASTM F920-85 |
| Average One Hand Tidal Volume: | >130 ml |
| Pop-off Valve Low: | Approx. 40 cm $H_2O$ (see step 3) |
| Pop-off Valve High: | >80 cm $H_2O$ |
| Ventilation Frequencies: | 60 BPM at 20 ml<br>40 BPM at 70 ml |
| PEEP Valve Range: | Calibrated Scale: 4 to 20 cm $H_2O$ ± 4 cm $H_2O$<br>Minimum: <3 cm $H_2O$<br>Maximum: >20 cm $H_2O$ |
| Patient Valve Deadspace: | <10 ml |
| Operating Environments: | -18°C to 50°C (0°F to 122°F) |
| Storage Environments: | -18°C to 50°C (0°F to 122°F) |
| Patient Adaptor: | 15 mm ID / 22 mm OD |
| Expiratory Pressure: | </=5 cm $H_2O$ (at5L/min patient flow) |
| Inspiratory Pressure: | </=5 cm $H_2O$ (at 5L/min reverse flow) |
| Backward Leakage: | <10% (per ASTM F920-85) |
| Unit Weight with Mask: | Approx. 340 grams |
| Unit Dimensions: | Approx. 11.5" L x 6"W x 3.5" H |

BagEasy is a registered trademark of Westmed, Inc.

BagEasy products are the subject of one or more of U.S. Patents:
#5,483,955, #5,501,214, #5,540,221, #5,546,934, and #5,558,371.

**REF** **562086**
**QTY: 1**

**BagEasy® Resuscitator**
Infant Resuscitator w/Mask

LOT

**Rx Only**

CE 0482

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Made in U.S.A.
Label PN 79421, Rev. 01

**INFANT**
BagEasy
Disposable Resuscitator

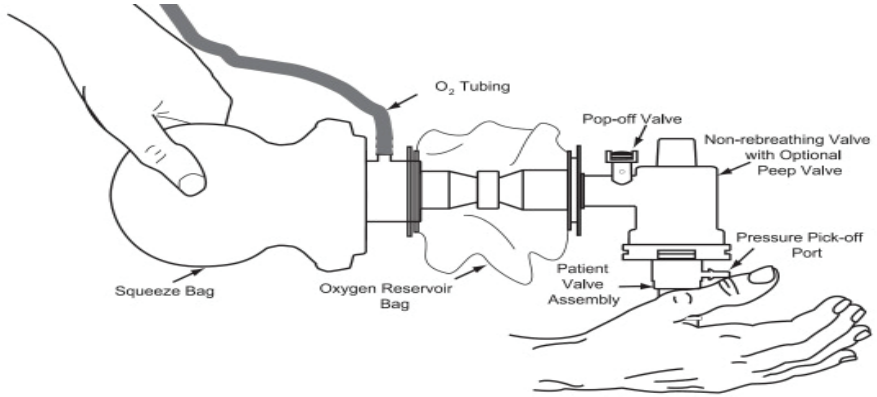
OPERATING INSTRUCTIONS

**⚠WARNING:**
**PERFORM FUNCTIONAL TEST ON RESUSCITATOR BEFORE USE.**

1. Remove the resuscitator from its protective packaging.
2. Squeeze the bag several times while viewing the patient valve assembly. The duckbill valve inside the patient valve assembly should open when the bag is squeezed and close while the bag refills. If the duckbill valve fails to open and close properly, **DO NOT USE THIS DEVICE**.
3. Occlude the patient valve. Do not connect to oxygen. Verify that the pop-off valve is set in the "High Pressure" position. Verify that the white port cap is on the pressure pick-off port on the patient valve assembly.
4. Hold the device in a horizontal position, with the oxygen port facing up. Squeeze the bag slowly and maintain compression for at least 3 – 5 seconds.

The oxygen reservoir bag should not inflate. The squeeze bag should deflate, but air should be venting through the pop-off valve ONLY. **IF THE DEVICE DOES NOT APPEAR TO BE FUNCTIONING PROPERLY, DO NOT USE THE DEVICE.** Repeat this test with another BagEasy.

These devices are not intended for reprocessing. Risk of reprocessing may include microbial contamination or product degradation.




Do not use this device in contaminated or volatile atmospheres, because these contaminants may be delivered to the patient.

Do not use oxygen near flammable materials, smoke, fire, or other potential sources of combustion. Oil or grease should not be used with the resuscitator.

BagEasy is intended for single patient use only. Do not attempt to decontaminate or sterilize.

BagEasy must never be stored in a deformed state.

The exact peak pressure in the airway when the pop-off valve is operational will depend on the rate of bag squeeze, the volume of air produced by the squeezing and the resistance and compliance of the airways.

Do not occlude the oxygen vent located on the perimeter of the oxygen reservoir. Blockage of vents will result in high exhalation resistance.

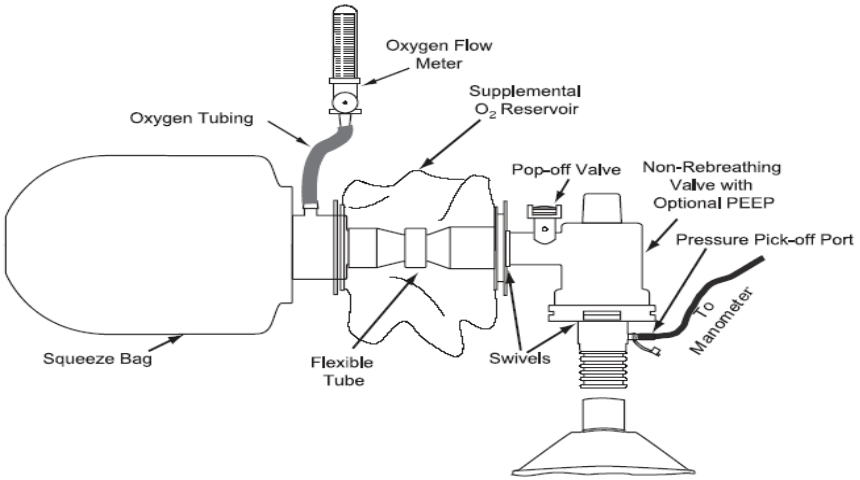
**USES**

BagEasy is indicated for patients requiring complete or intermittent ventilatory support. It can provide positive pressure ventilation or oxygen for the patient breathing spontaneously with a face mask or through an artificial airway.

BagEasy is a **SINGLE PATIENT USE DEVICE**, shipped clean but not sterilized.

**DIRECTIONS FOR USE**

*Read all instructions before using this product*




Follow accepted procedures for creating a patent airway.

STEP 1 – Connect the oxygen tubing to a flowmeter. Set a flowrate of 5 to 10 L/min.

STEP 2 – Each Infant BagEasy is shipped with a pressure pick-off port built into the patient connector. To monitor airway pressures, remove the white cap from the pressure pick-off port and connect a manometer. USE ONLY TUBING WITH SMOOTH INNER WALLS. TUBING WITH AN INTERNAL STAR LUMEN COULD CAUSE INACCURATE PRESSURE READINGS. The manometer can also be used to verify the pop-off valve and PEEP pressures. If you are not monitoring pressures, check to assure that the pressure pick-off port is capped.

STEP 3 – Observe the pop-off valve control lever to ensure that it is in the desired position. To activate, flip the control lever so the side that shows the words "40 cm $H_2O$" is facing up. Occlude the patient connector. Squeeze the bag and verify the pop-off valve function. The exact pressure in the airway when the pop-off valve is operational will depend on the rate of bag squeeze, the volume of air produced by the squeezing, and the resistance and compliance of the system.

STEP 4 – If using a mask, maintain airway using appropriate technique. Connect the unit to a mask or to an artificial airway via the 22 mm male/ 15 mm female connector.

STEP 5 – Compress the self-inflating squeeze bag as the patient inspires or at a rate appropriate for the patient's condition. Observe the patient for adequacy of chest rise and fall. Should vomitus obstruct the valve, remove the unit from the patient, then quickly and forcefully squeeze the bag with maximum effort to clear the valve. Tap the valve if needed. Any residual material may be rinsed away with water. When BagEasy is no longer needed, disconnect from airway or mask by holding the swivel while supporting the artificial airway to avoid excessive movement or distortion.

**OPTIONAL BUILT IN PEEP VALVE**

BagEasy with Built In Positive End Expiratory Pressure (PEEP) valves are shipped clean. They are not sterilized.

**Description**

BagEasy provides a threshold resistor-type PEEP valve that allows the operator to deliver variable positive end expiratory pressure. If PEEP is not desired, set the indicator at the MINIMUM marking on the pressure scale label.

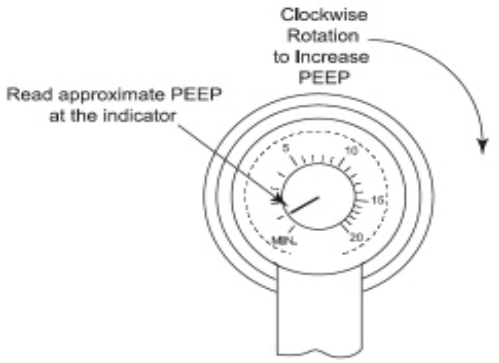
**Indications**

PEEP can be used for improving oxygenation in patients who do not adequately respond to increased inspired oxygen levels.

**PEEP Valve Operating Instructions**

STEP 1 – Adjust the knob on the PEEP valve to achieve the desired PEEP levels. Clockwise rotation will increase PEEP levels.

STEP 2 – Observe the position of the adjustment knob indicator in relation to the pressure scale label to determine the approximate amount of PEEP being generated. Actual PEEP may vary with patient lung compliance and resistance. Therefore, verify PEEP pressure with a manometer.




## ⚠ WARNINGS AND PRECAUTIONS

Federal law restricts this device to sale by or on the order of a physician.

Use of this product on other than Pediatric patients (7-30 kg) may result in the delivery of inadequate tidal volume.

This device is to be operated only by medical personnel specifically trained in the use of manual resuscitators. Improper bag use or function could lead to inadequate ventilation, resulting in serious injury or death. Read all instructions and test each unit prior to use. (see front cover)

Verify that the pressure pick-off port is either capped with the white cap or connected to a manometer. Failure to plug the pressure pick-off port may result in inadequate tidal volumes.

DO NOT USE PEEP unless you have been thoroughly trained in the indications, contraindications, and side effects of PEEP therapy and unless it has been ordered by a physician. Close observation and reliable assessments are essential when using PEEP in patients with low circulatory blood volume, impaired cardiac function, bullous lung disease, or higher than normal lung compliance. Assess the patient's hemodynamic, ventilatory and oxygenation status when using PEEP.

Always monitor PEEP and ventilation pressures with a manometer.

Very high incoming oxygen flow rates may result in inadvertent PEEP. For example, at 30L/min $O_2$ flow rate, inadvertent PEEP may exceed 3 cm $H_2O$.

When using this device on a spontaneously breathing patient, failure to ventilate by following the patient's ventilatory pattern may create excessive airway pressure.

If cervical spine injury is suspected, use accepted techniques to create a patent airway.