SINGLE PATIENT USE ONLY

ADULT BAGEASY SPECIFICATIONS

Applicable Patient Size:	>30 kg (>66 lbs)
O_2 Concentrations*	
>93% at 15 L/min O_2 flow; typical values of 97% to 99%	
*Tested per ASTM F920	
Average Tidal Volume:	One hand >650 ml Two hand >1000 ml
Ventilation Frequencies:	20 BPM at 650 ml 12 BPM at 900 ml
PEEP Valve Range: Calibrated Scale:	
	4 to 20 cm H_2O ± 4 cm H_2O
	Minimum: <3 cm H_2O
	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 (at 50 L/min patient flow):	</= "5 cm H_2O
Inspiratory Pressure (at 50 L/min reverse flow):	</= "5 cm H_2O
Backward Leakage (per ASTM F920-85):	<1%
Unit Weight with Mask:	Approx. 500 grams
Unit Dimensions (Open):	Approx. 15" L x 6" W x 5" H
Unit Dimensions (Folded):	Approx. 10" L x 6" W x 5" H

REF 562048 **BagEasy® Resuscitator**
QTY: 1 Adult BagEasy Resuscitator w/Peep and Mask

LOT

Rx Only

0482

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EC REP

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Made in U.S.A.
LABEL PN 79411, Rev. 01

ADULT

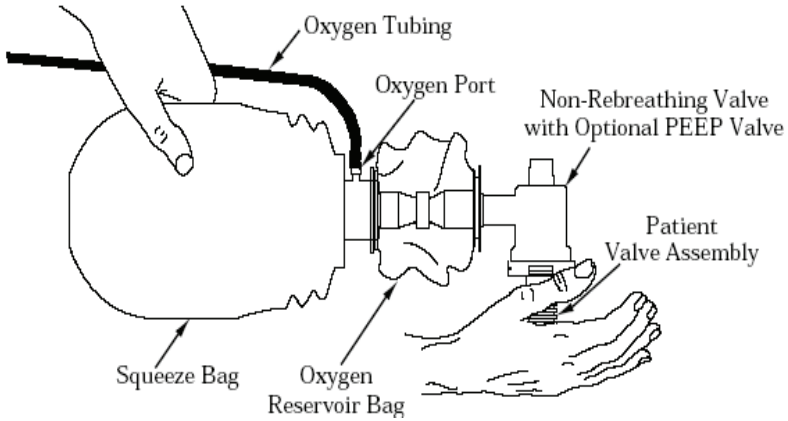
BagEasy
Disposable Resuscitator

OPERATING INSTRUCTIONS

⚠ WARNING:
PERFORM FUNCTIONAL TEST ON RESUSCITATOR BEFORE USE.

1. Remove the resuscitator from its protective packaging. Make certain that the squeeze bag is fully extended by gripping the squeeze bag with one hand on the non-rebreathing valve with the other hand; pull the valve away from the squeeze bag.
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.
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. If the oxygen reservoir bag inflates or the squeeze bag deflates, not allowing 3-5 seconds of compression, **DO NOT USE THIS DEVICE**. Repeat this test with another BagEasy.

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



BagEasy is intended for single patient use only. Do not attempt to decontaminate or sterilize. Do not store the BagEasy such that the squeeze bag or flex tube is deformed in any way. For example, do not place equipment on an unfolded BagEasy; do not store an unfolded BagEasy in a confined area requiring compression of the BagEasy.
The exact peak inspiratory pressure in the airway will be dependent on the rate of bag squeeze, the volume of air produced by the squeezing, and the resistance and compliance of the airways. For example, when tested on a test lung model at an inspiratory time of one second, tidal volume of 600 ml, a resistance of 20 cm H_2O/l/sec, and a compliance of 0.02 L/cm H_2O, the peak airway pressure is approximately 30 cm H_2O.

⚠**CAUTIONS!** Indicates the possibility of damage to the device.
Do not occlude the oxygen vents located on the perimeter of the oxygen reservoir. Blockage of vents will result in high exhalation resistance.
In extreme cold (below 0° C) the squeeze bag may require more effort to unfold.

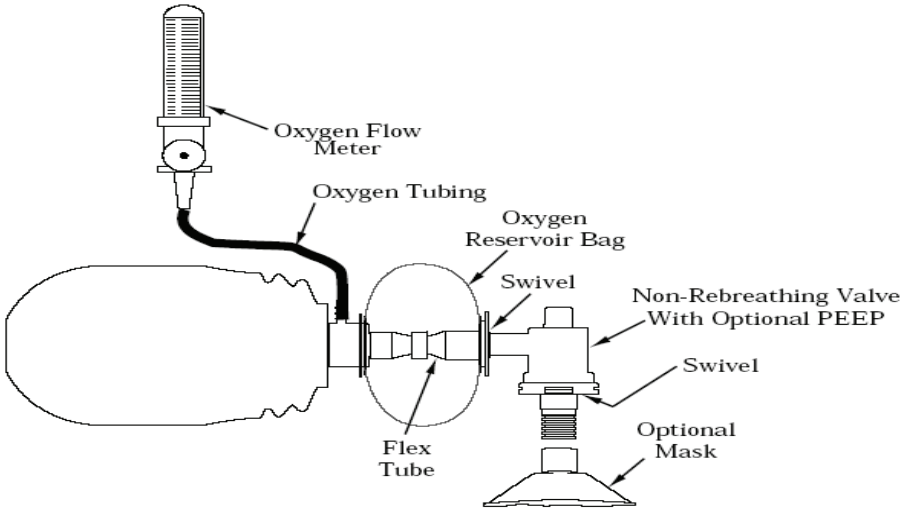
DESCRIPTION

BagEasy provides intermittent manual ventilatory support with or without supplemental oxygen. The Adult BagEasy design is suitable for use on patients weighing greater than 30 kg (66 lbs). The Adult BagEasy contains no latex.

USES

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

Rx Only



DIRECTIONS FOR USE

Read all instructions before using this product
Follow accepted procedures for creating a patent airway.
STEP 1 – Connect the attached oxygen tubing to a flowmeter. Set a flow rate of 12 to 15 L/min, or according to your hospital protocol.
STEP 2 – If using a mask, ensure patent airway is maintained using appropriate technique. Make certain the squeeze bag is fully open and extended. Connect the bag to a mask or to an artificial airway via the 22 mm male / 15 mm female connector.
STEP 3 – Compress the self-inflating squeeze bag as the patient inspires or at a rate appropriate for the patient's condition. Monitor ventilation pressures with a manometer. Observe the patient for adequacy of chest rise and fall, improvement or maintenance of skin color, and other indications of adequate ventilation. Should vomitus obstruct the valve, disconnect 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. Once BagEasy is no longer needed, disconnect from airway or mask by holding the swivel while supporting the artificial airway to avoid excessive movement.

Optional Built in Peep Valve

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

Description

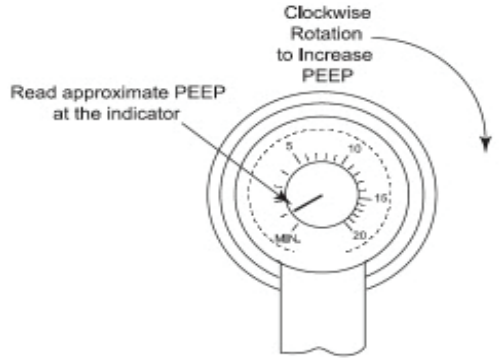
BagEasy provides a threshold resistor-type PEEP valve that allows the operator to deliver variable positive end expiratory pressure. If PEEP is not desired, set the indicator at the MINIMUM marking on the pressure scale label.

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.
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)
Do not use PEEP unless you have been thoroughly trained in the indications, contraindications, and side effects of PEEP therapy and 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 30 L/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.
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.