

Smart Bag[®] Mo

“Improving ventilation, one breath at a time”!



01BM3100-MO



01BM3110-MO



01BM3400-MO



01BM3410-MO



01BM3201-MO-Cs



01BM3211-MO-Cs

Ordering information:

- 01BM3100-MO Silicone SMART BAG[®] MO (Adult) c/w Facemask and Reservoir System (Each)
- 01BM3110-MO Silicone SMART BAG[®] MO (Child) c/w Facemask and Reservoir System (Each)
- 01BM3400-MO Cold Chemical Sterilizable SMART BAG[®] MO (Adult) c/w Facemask and Reservoir System (Each)
- 01BM3410-MO Cold Chemical Sterilizable SMART BAG[®] MO (Child) c/w Facemask and Reservoir System (Each)
- 01BM3201-MO-Cs Disposable SMART BAG[®] MO (Adult) c/w Facemask and Reservoir System (Case/6)
- 01BM3211-MO-Cs Disposable SMART BAG[®] MO (Child) c/w Facemask and Reservoir System (Case/6)

Your Representative is:



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“Improving ventilation, one breath at a time”!



01BM3201-MO-Cs



Bag Valve Mask Ventilation

THE PROBLEM

Since its introduction, the Bag-Valve-Mask resuscitator (or BVM) has been the mainstay of emergency ventilation in both the pre-hospital and hospital environments. However, the clinical evidence regarding the performance of these devices however shows a marked lack of control over the ventilation parameters in the hands of the majority of users.^{1,2,3,4,5,6} More recent research has compounded this lack of supporting evidence regarding the efficacy of these devices with studies that have shown the clinically detrimental effects of what is now termed, Inadvertent Hyperventilation.

This common phenomenon is defined as the unintentional (involuntary, accidental or not deliberate) delivery of an excessive minute volume. It is likely to have detrimental hemodynamic and survival consequences in patients in low flow states such as during CPR or hypovolemia due to trauma.

Gastric insufflation and the associated risk of aspiration of stomach contents, decreased coronary perfusion pressure¹⁰ and increased brain ischaemia¹¹ are all shown to be caused by inadvertent hyper-ventilation.

The decrease in coronary perfusion pressure is a result of the mechanical "squeezing" of the heart by either too large a tidal volume delivery or "breath stacking" (insufficient expiratory time allowed for the lungs to fully empty resulting in the subsequent breath being "stacked" on a residual volume from the preceding breath).

Increased brain ischemia is a function of excessive CO₂ removal creating an increase in cerebral vasoconstriction.

Add to these issues poor oxygenation and the affect on patient outcomes becomes significant, even to the point of contributing to the currently poor survival rates from Cardiac Arrest.¹²

THE SOLUTION

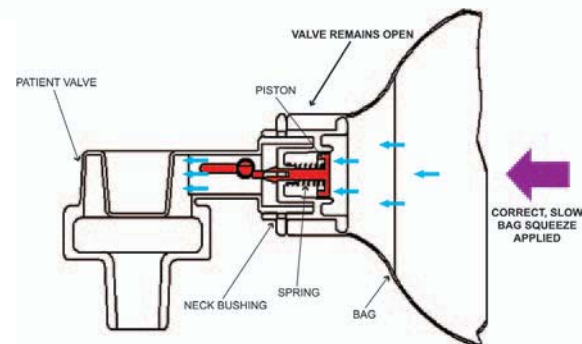
SMART BAG® MO has been designed to allow the provision of consistent ventilations while almost completely eliminating the risks associated with conventional BVM ventilation. The simplicity of the design masks the complexity of the technology that makes **SMART BAG® MO** so effective.

The unique actuating mechanism hidden inside the neck bushing of the **SMART BAG® MO** actually responds to the rescuer and the patient!

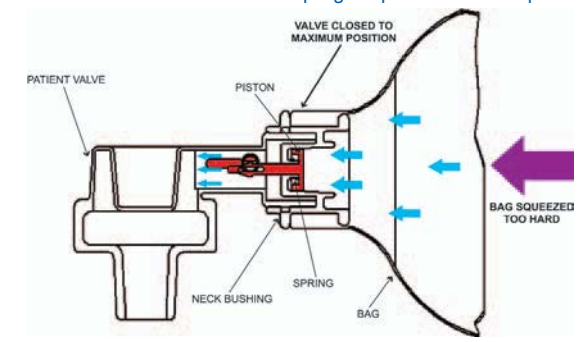
RESPONDING TO YOU

By responding to the rescuer's squeeze and release of the BVM, the **SMART BAG® MO** limits the excessive flow of gas into the patient's airway, significantly reducing the risk of gastric insufflation by effectively lowering the airway pressure generated. In a normally compliant and resistant airway, the airway pressure generated is limited to below the lower esophageal sphincter opening pressure of 19 cm H₂O.

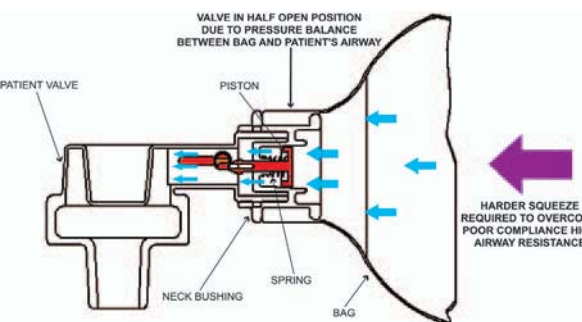
The response by the **SMART BAG® MO** is proportional to the rescuer's squeeze. The harder the squeeze the greater the restriction to flow. This alerts the rescuer to ease up on the squeeze, reducing the effort required, resulting in the airway pressure being kept to the minimum to achieve adequate ventilation. At no time is the flow of gas into the patient compromised by the **SMART BAG® MO**, allowing the rescuer to ventilate even the stiffest lung or most restrictive airway! To aid the rescuer a visual warning of incorrect operation of the bag is provided. If the bag is squeezed too hard the **SMART BAG® MO** responds by closing the valve to lower the flowrate. Should this occur the "red pressure actuation indicator" moves to a forward position in the neck of the patient valve providing a visual warning of improper technique.



PATIENT WITH NORMAL COMPLIANCE AND RESISTANCE
Flowrate is controlled by the force applied to the bag by the rescuer. Airway pressure is maintained below lower esophageal sphincter threshold pressure.



PATIENT WITH NORMAL COMPLIANCE AND RESISTANCE
Flowrate is restricted by the **SMART BAG® MO** to maintain a low airway pressure. The visual Indicator will move forward into the patient valve reminding the rescuer to reduce the force being applied to the bag.



PATIENT WITH POOR COMPLIANCE / HIGH AIRWAY RESISTANCE
Due to the patient's airway condition a higher pressure than normal is required to overcome the poor compliance/high airway resistance. **SMART BAG® MO** senses the change in the patient's condition and balances the resistance to flow through the valve allowing the rescuer to apply higher flows to the airway and adequately ventilate the patient.

NOTE: This increase in airway pressure required to provide adequate ventilation may allow gas to be diverted into the patient's stomach as the lower esophageal sphincter pressure is exceeded.

RESPONDING TO YOUR PATIENT

If the patient's airway is less compliant or more restrictive (as in patients with COPD or asthma), higher airway pressures will be required to provide adequate ventilation.

In responding to this increased pressure requirement in the patient's airway, the **SMART BAG® MO** allows the user to increase the pressure required to overcome the resistance/compliance problem and provide adequate ventilations.

Remember that the **SMART BAG® MO** will only allow you to apply higher flowrates generating higher airway pressures when the patient's airway condition requires them. You will "feel" this change in compliance and resistance as the **SMART BAG® MO** allows the higher flowrates to be generated.

NOTE: In the unprotected airway, as with any resuscitation device, the risk of gastric insufflation will increase if the delivered flowrate increases the airway pressure generated above the LES opening pressure.

PROVIDING CONTROLLED VENTILATION

By "self adjusting" to both the patient and the rescuer, the **SMART BAG® MO** optimizes the ventilations, controlling the inspiratory time and keeping the delivered flowrate and subsequent airway pressure to the minimum required for adequate ventilation to occur. This results in a significant reduction in the risk of gastric insufflation and its associated complications.

USING THE SMART BAG® MO

Using the **SMART BAG® MO** is **EASY!** Just let **SMART BAG® MO** compress under your gentle, slow, hand squeeze. A one or two-handed squeeze can be used. The Inspiratory time should be 1 second in accordance with the current international resuscitation guidelines.

TRAINING AND SKILL RETENTION

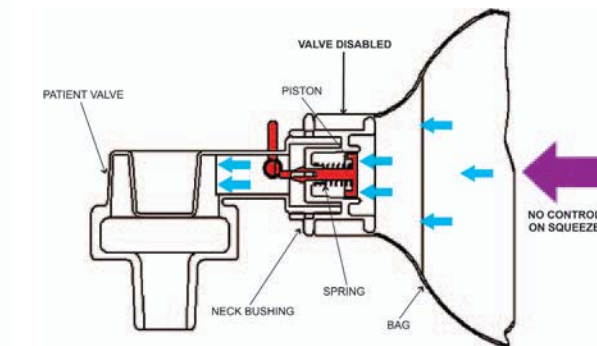
Many references exist as to the ability of rescuers to adequately perform practical skills. In addition, the retention of those skills and the ability to adequately perform them, overtime, decreases without frequent re-training and education.

By imparting a degree of control for the rescuer the **SMART BAG® MO** helps to train the rescuer to provide slow consistent ventilations. In addition, the **SMART BAG® MO** continually re-trains the rescuer every time they use the device by imparting that same degree of control during resuscitation.

THE USE OF MANUAL OVERRIDE CONTROL DURING INTUBATED CPR

The Manual Override ("disable") control has been provided to assist the rescuer in providing guidelines compliant ventilation/compression ratios in the intubated patient. Once intubated, it is recommended that the **SMART BAG® MO** be used in the "disabled" mode with the action of the piston blocked by rotating the manual override control lever to the "up" position. If the patient is in respiratory arrest only it is recommended that the **SMART BAG® MO** be used in the "enabled" mode with the indicator arm of the manual override control in line with the direction of the gas flow. This will allow the **SMART BAG® MO** to assist the rescuer in providing controlled ventilations. In the mask ventilated patient, should the rescuer identify that an adequate mask-to-face seal cannot be achieved or that the patient's respiratory condition is such that high flowrates are required to provide adequate ventilation, the **SMART BAG® MO** can be switched into the "disabled" mode.

NOTE: To ensure correct operation of the manual override, do not switch into the disabled mode while squeezing the bag.



SMART® Valve "Disabled," **SMART BAG® MO** responds like a standard BVM.



NOTES:

[1] Manual resuscitators are not usually intended as an oxygen source for spontaneously breathing patients, because the resistance of the conventional valves in the resuscitator may be excessive, and the oxygen delivery during spontaneous ventilation cannot be assured. Nevertheless, the patient may breathe spontaneously during manual ventilation in some circumstances. If the patient is breathing spontaneously during manual ventilation, the flow limiter lever should be switched to the "disabled" position to allow the inspiratory resistance to be minimized.

[2] Because of the unique nature of the **SMART BAG® MO**, new users will require minimal training. This is due to the **SMART BAG® MO** offering a level of control for your ventilations never before provided by a BVM. Squeezing the bag gently will reduce the bag tension allowing a more comfortable squeeze, ensuring that the airway pressure is being kept to the minimum required to achieve adequate ventilation, and reducing the risk of gastric insufflation.

[3] Using the **SMART BAG® MO** in the disabled mode on a mask ventilated patient may result in gastric insufflation.

WARNING: The resuscitator is not intended for use during spontaneous breathing. The resuscitator will provide room air and little or no supplemental oxygen during spontaneous breathing.

References:

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5. Wheatley S, Thomas AN, Taylor RJ, Brown T. A comparison of three methods of bag valve mask ventilation. *Resuscitation* 1997 Jan;33(3):201-10
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8. Brain Trauma Foundation. Guidelines for the Management of Severe Head Injury - 1995
9. Pitts and Kellerman. Editorial in the *Lancet* July 24th 2005