

Smart Bag® Mo

"Improving ventilation, one breath at a time"!



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:

Smart Bag® Mo

"Improving ventilation, one breath at a time"!



01BM3201-MO-Cs



15PL2136Rev. 4 11/04



O-TWO MEDICAL TECHNOLOGIES INC.
 "INNOVATION IN RESUSCITATION"

7575 Kimbel Street, Mississauga, Ontario, Canada L5S 1C8
 Toll Free: (800) 387-3405 Tel: (905) 677-9410 Fax: (905) 677-2035
 E-mail: resuscitation@otwo.com
 Website: www.otwo.com



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.^{3,4,5} 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 pressure⁶ and increased brain ischaemia⁷ are all shown to be caused by inadvertent hyperventilation.

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

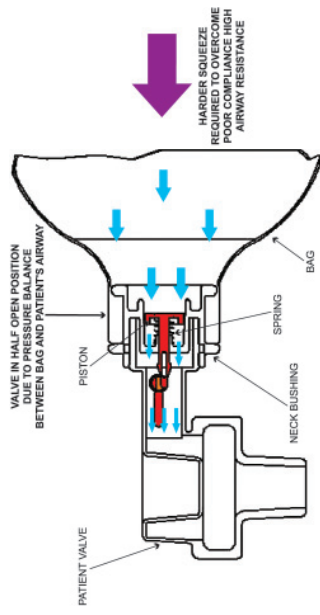
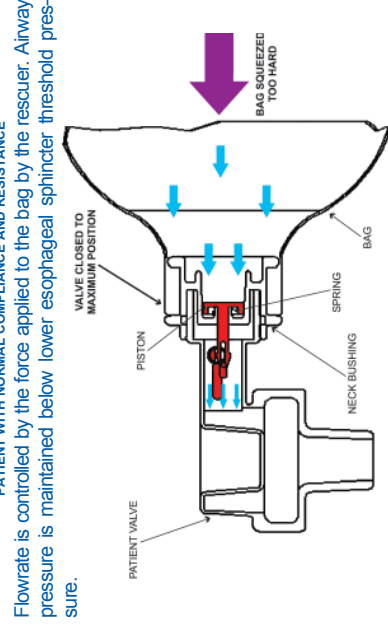
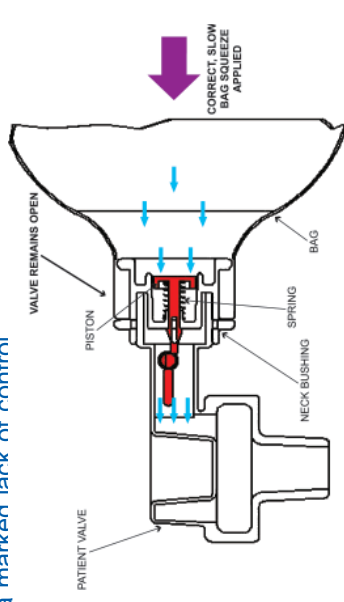
SMART BAG® MO has been designed to allow the provision of consistent ventilations while almost completely eliminating the risks associated with conventional BVM ventilation. The simplicity of the design masks the complexity of the technology that makes **SMART BAG® MO** so effective.

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 rescuers 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.



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 it's 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 guide lines.

TRAINING AND SKILL RETENTION

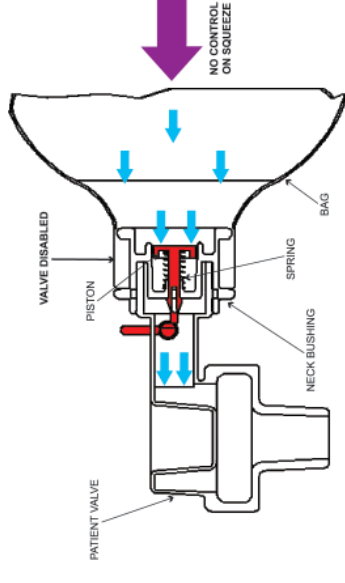
Many references exist as to the ability of rescuers to adequately perform practical skills. In addition, the retention of those skills and the ability to adequately perform them, overtime, decreases without frequent re-training and education.

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

Current research indicates that, for all patient conditions, the **Manual Override** control should **NOT BE USED** and the “**SMART VALVE**” should be left in the “**ENABLED**” position. This recommendation maintains operation of the **SMART BAG® MO** in strict compliance with the current Guidelines for CPR and ECC as published by the American Heart Association and the European Resuscitation Council.

Should the operator decide to use the manual override control, it is important not switch into the disabled mode while squeezing the bag. Using the **SMART BAG® MO** in the “**SMART VALVE**” “**ENABLED**” mode may result in “inadvertent hyperventilation” with all its associated risks.



SMART Valve “Disabled,” SMART BAG® MO responds like a standard BVM.



NOTES:

[1] Because of the unique nature of the **SMART BAG® MO**, new users will require minimal orientation in the use of the device.

[2] The resuscitator is not intended for use during spontaneous breathing. Due to the nature of these devices, they may only provide a restricted flow of air to the patient and little or no supplemental oxygen.

References:

1. A.H.A. Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care – 2005
2. Eiling R, Politis J. An evaluation of emergency medical technicians' ability to use manual ventilation devices. Ann Emerg Med. 1983;12:765-768
3. Hess D, Baran C. Ventilatory volumes and bag-valve-mask techniques. Am J Emerg Med 1985;3:292-296
4. Jesudian MC, Harrison RR, Keenan RL, Mauli KI. Bag-valve-mask ventilation: two rescuers are better than one: preliminary report. Crit Care Med. 1985;13:122-123
5. Whealley S, Thomas AN, Taylor RJ, Brown T. A comparison of three methods of bag valve mask ventilation. Resuscitation 1997;Jan;33(3):201-10
6. Fuerst RS, Banner MJ, Melker RJ. Inspiratory time influences the distribution of ventilation to the lungs and stomach: implications for C.P.R. Presented at the Society for Academic Emergency Medicine Annual Meeting, May 1992.
7. Audebrand T, et al: Hyperventilation-Induced Hypotension During Cardiopulmonary Resuscitation. Circulation April 27, 2004
8. Brain Trauma Foundation. Guidelines for the Management of Severe Head Injury - 1995
9. Pitts and Kellerman. Editorial in the Lancet July 24th 2005