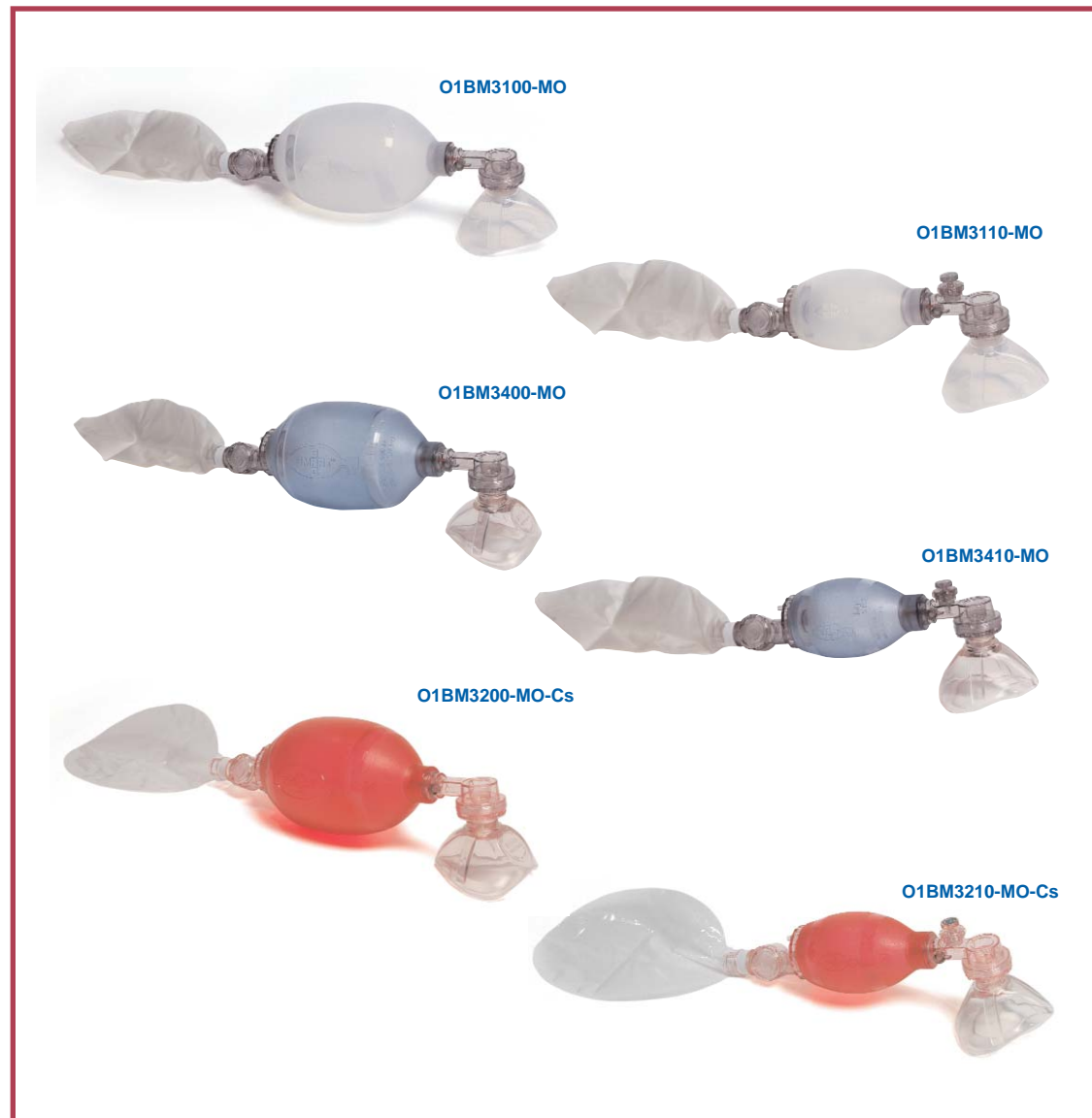


# SMART BAG® MO

“A 21<sup>ST</sup> century solution to a 40 year old problem!”



# SMART BAG® MO

(Synchronized Manual Actuation Response Technology)

*“The Most Revolutionary Advance in BVM Performance in over 40 Years!”*

*Controlled Flowrate!  
Controlled Airway Pressure!  
Controlled Pressure!  
Reduced Risk of Gastric Insufflation!  
Manual Override Option!*

#### 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)
01BM3200-MO-Cs	Disposable SMART BAG® MO (Adult) c/w Facemask and Reservoir System (Case/6)
01BM3210-MO-Cs	Disposable SMART BAG® MO (Child) c/w Facemask and Reservoir System (Case/6)

Your Representative is:



**O-Two Medical Technologies Inc.**

“Innovation in Resuscitation”

7575 Kimbel Street  
Mississauga, Ontario, Canada L5S 1C8  
In N.A. Toll Free: (800) 387-3405

Tel: (905) 677-9410 Fax: (905) 677-2035

E-mail: [resuscitation@otwo.com](mailto:resuscitation@otwo.com) Website: [www.otwo.com](http://www.otwo.com)

15PL2136Rev. 4 11/04



**Now That's Smart!**

# SMART BAG<sup>®</sup> MO

SYNCHRONIZED MANUAL ACTUATION RESPONSE TECHNOLOGY

## BAG VALVE MASK VENTILATION

### THE PROBLEM

Since its original introduction, the Bag-Valve-Mask resuscitator (or BVM) has been the mainstay of emergency ventilation in both the pre-hospital and hospital environments. 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.<sup>1,2,3,4,5,7</sup>

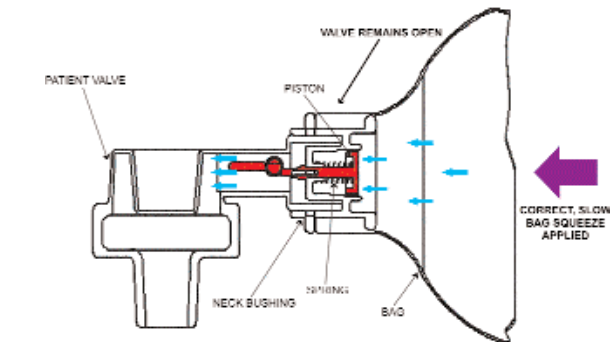
In the unprotected airway, this lack of control includes:

- o Very high flowrates generated by squeezing the BVM too hard and/or too fast causing high airway pressures.<sup>6</sup>
- o Gastric insufflation caused by gas being diverted into the stomach as these high airway pressures overcome the lower esophageal sphincter (LES) opening pressure.
- o The subsequent vomiting and aspiration of stomach contents with all the complications for the patient that this entails.
- o Reduced tidal volume delivery (because of partial volume going into stomach.)
- o Barotrauma – even in the protected airway (LMA, E-T tube, E-O tube etc.) high ventilation pressures can lead to barotrauma.

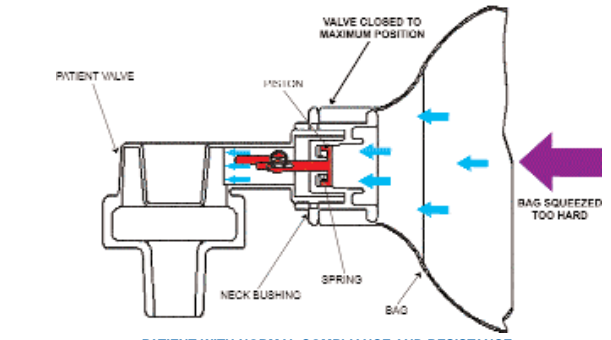
In addition, the uncontrolled and inconsistent ventilation frequencies and short inspiratory and expiratory times that are normally delivered using a standard BVM lead to poor ventilation, poor CO<sub>2</sub> removal, increased respiratory alkalosis and poor oxygenation.<sup>8,9</sup>

### THE SOLUTION

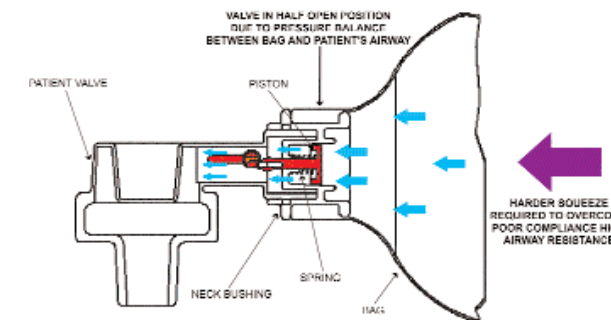
SMART BAG<sup>®</sup> MO has been designed to allow the provision of consistent ventilations while almost completely eliminating the risks associated with conventional BVM ventilation. The simplicity of the design masks the complexity of the technology that makes SMART BAG<sup>®</sup> MO so effective.



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<sup>®</sup> 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<sup>®</sup> 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.

The unique actuating mechanism hidden inside the neck bushing of the SMART BAG<sup>®</sup> 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<sup>®</sup> 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 H<sub>2</sub>O.

The response by the SMART BAG<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> MO allows the user to increase the pressure required to overcome the resistance/compliance problem and provide adequate ventilations.

Remember that the SMART BAG<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> MO

Using the SMART BAG<sup>®</sup> MO is EASY! Just let SMART BAG<sup>®</sup> MO compress under your gentle, slow, hand squeeze. A one or two-handed squeeze can be used. The Inspiratory time should be 1.5 to 2 seconds in accordance with 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.

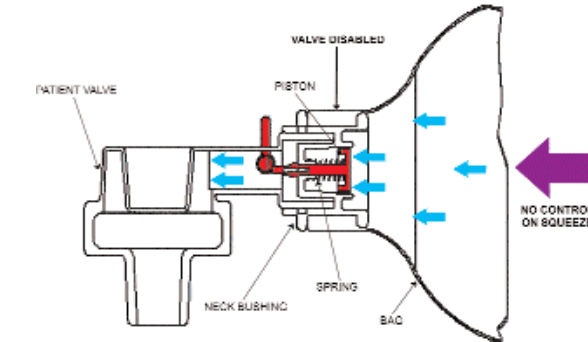
By imparting a degree of control for the rescuer the SMART BAG<sup>®</sup> MO helps to train the rescuer to provide slow consistent ventilations. In addition, the SMART BAG<sup>®</sup> MO continually re-trains the rescuer every time they use the device by imparting that same degree of control during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

### FACEMASKS LEAKAGE, UNCOMMON PATIENT CONDITIONS AND THE USE OF MANUAL OVERRIDE

The Manual Override ("disable") has been provided to assist the rescuer in overcoming massive facemask leakage due to the inability to effect a positive mask-to-face seal or when confronting uncommon patient conditions.

Ventilations should always be initiated with the SMART BAG<sup>®</sup> MO 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<sup>®</sup> MO to provide the controlled flowrates that reduce the risks of gastric insufflation and barotrauma. 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<sup>®</sup> MO can be switched into the "disabled" mode by rotating the indicator arm upwards, 90° to the direction of the gas flow, disabling the SMART<sup>®</sup> technology. Once intubated it is recommended that the SMART BAG<sup>®</sup> MO be used in the "enabled" mode.

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



SMART<sup>®</sup> Valve "Disabled," SMART BAG<sup>®</sup> MO responds like a standard BVM.



References:

1. A.H.A Guidelines for cardiopulmonary Resuscitation and Emergency Cardiac Care – September 2000
2. Elling 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 using mouth to mouth, mouth to mask and bag-valve-mask techniques Am J Emerg Med 1985;3:292-296.
4. Jesudian MC, Harrison RR, Keenan RL, Maul K. Bag-valve-mask ventilation: two rescuers are better than one: preliminary report. Crit Care Med. 1985;13:122-123
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
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. Melker RJ, Banner J. Ventilation during CPR: two rescuer standards reappraised. Am. Emerg. Med. 14:397-402
8. Hurst JM, Davis K Jr, Branson RD, Johannigman JA. Comparison of blood gases of ventilated patients during transport. J Trauma. 1989;29:1637-1640.
9. Gervais HW, Eberle B, Konietzke D, Hennes HJ, Dick W. Comparison of blood gases of ventilated patients during transport. Crit Care Med 1987;15:761-763.

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 because 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. This resuscitator will provide room air with little or no supplemental oxygen during spontaneous ventilation."

[2] Because of the unique nature of the SMART BAG<sup>®</sup> MO, new users will require minimal training. This is due to the SMART BAG<sup>®</sup> 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.

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