

# SOTAIR CLINICAL DEVICE

6 Pack

## Ensuring That Air Delivery Stays Within Safe Limits

SafeBVM's flagship innovation, the award-winning Sotair® device, is primarily funded by grants and contracts from the National Institutes of Health (NIH), National Science Foundation (NSF), and the Military.

Sotair is a small, lightweight, easy to use flow control valve that fits between a manual resuscitator and a patient mask or airway. The valve prevents flow rates of air from exceeding 55 LPM during manual ventilation, ensuring that air delivery stays within safe limits. Flow control helps reduce peak airway pressures, excessive tidal volumes and excessive breath delivery rates, minimizing the risk of over-pressurization, over-ventilation and hyperventilation.

Because the Sotair is a flow limiting device, it automatically adjusts peak pressure based on the patient's airway and lung compliance, making it suitable for any adult patient (e.g. Asthma, COPD, ARDS Pneumothorax). For example, in a patient with healthy lungs and normal airways, Sotair caps peak pressures around 20–22 cmH<sub>2</sub>O, just below the threshold where air could enter the stomach during manual ventilation. In patients with increased airway resistance, (e.g., asthma, COPD), or restrictive lung diseases (e.g., pulmonary fibrosis, obesity hypoventilation syndrome), Sotair automatically adjusts the peak pressure limit to meet their specific needs.

**How Sotair works:** If the bag is squeezed too quickly or forcefully causing inspiratory flow to exceed 55 LPM, Sotair's valve closes, creating a resistance in the bag producing alarms realized by the user. Alarms are tactile and/or auditory with visual cues and prompts the user to adjust their technique encouraging the right actions, avoiding rapid, forceful squeezes that lead to unsafe ventilation. This intuitive feedback makes training easy and reinforces best practices tailored to different patient lung conditions during real-time clinical use.

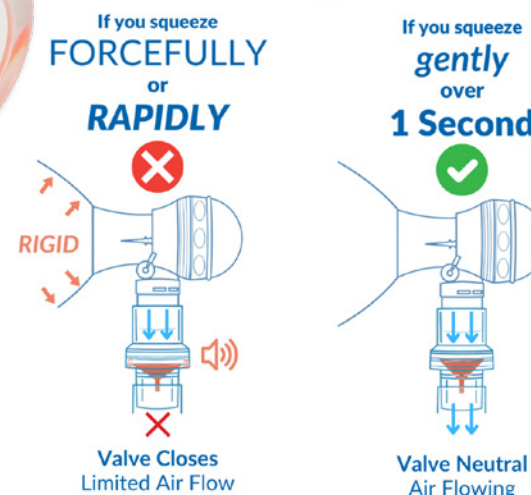
## FEATURES/SPECIFICATIONS

- Comes in a box of 6
- Fits between a manual resuscitator and a patient mask/airway
- Flow rates of air are limited to 55 LPM
- Regulation of airflow helps reduce peak airway pressures, excessive tidal volumes<sup>1</sup> and excessive breath delivery rates,<sup>2</sup> minimizing the risk of over-pressurization, over-ventilation and hyperventilation
- Peak Pressure limit during air delivery is automatically adjusted based on the patient's lung compliance and resistance
- Acts as a 'Forcing Function,' constraining the provider to deliver safer manual ventilation with less variability. This is most effective in ensuring system-wide change
- Immediate real-time tactile and auditory alarms with visual cues
- Decreases provider variability and improves consistency of ventilation
- Reliable performance: 100% activation and flow limiting testing
- 30 second basic training
- FDA 510(k) cleared for adult, single patient use

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**Device Only. Accessories not included.**



## SOTAIR CLINICAL DEVICE

ITEM #

10-0083

\* Sotair Training Device (REF# 10-0082) also available at [www.NARescue.com](http://www.NARescue.com)

## DIMENSIONS

- Dimensions: L 6.18 in. x W 4.29 in. x D 2 in.
- Weight: 0.35 lbs.



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