safeBVM

INSTRUCTIONS FOR USE
ADULT Sotair™ Device

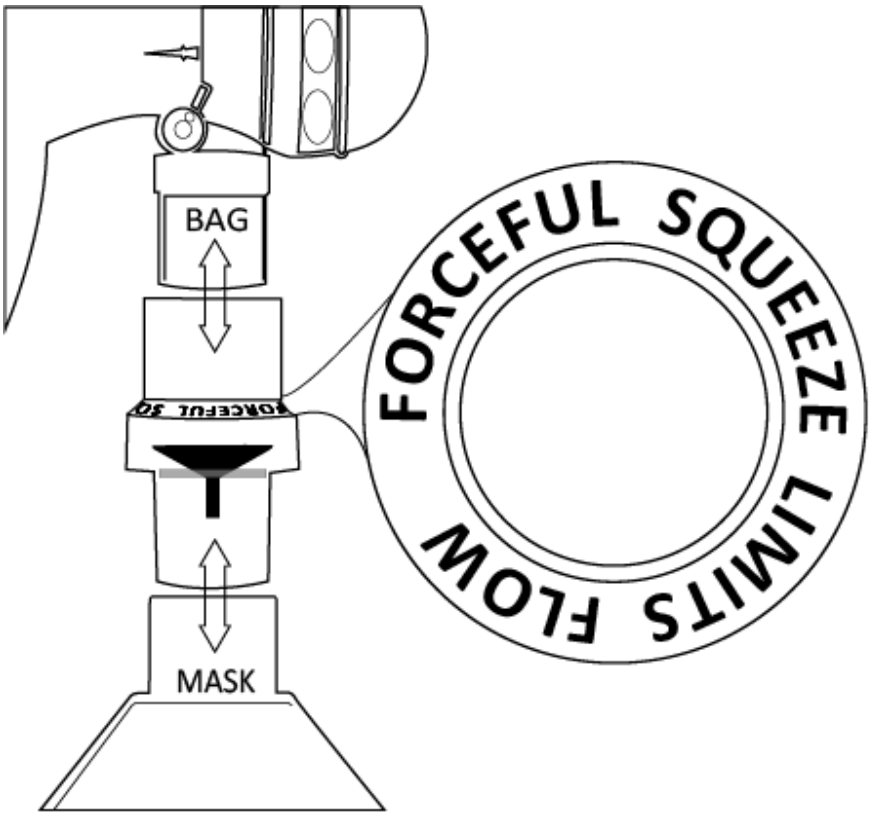
PRODUCT DESCRIPTION:
The Sotair device is a disposable add-on device to a manual resuscitator.

INTENDED USE:
The Sotair device is intended for use with a manual resuscitator with air-tight connections, in non-breathing patients that require flow controlled ventilation using ambient air or a supplemental oxygen source. The Sotair device is a single use, disposable device added to a manual resuscitator and can be used for in-hospital, emergency, and transport care. The adult Sotair device comprises a flow-limiting valve that limits the inspiratory flow enabling users to ventilate at approximately 55 liters-per-minute (LPM). The flow-limiting valve is intended to minimize gastric inflation during manual ventilation. The Sotair device can be disabled by removing the device, thereby returning the manual resuscitator to its conventional operation. The Sotair device is for ADULT use only.

WARNINGS and PRECAUTIONS

- To be used only by personnel trained in CPR procedures.
- For single patient use only.
- Prior to use, perform the steps outlined in the TEST OF FUNCTION section on Page 3.
- Incorrect operation of this device can be hazardous.
- For use with manual resuscitators with an airtight mask seal.
- The Sotair device is not intended for use during spontaneous ventilation. The resuscitator will provide room air and little or no supplemental oxygen during spontaneous ventilation.
- Manual resuscitators are not usually intended as an oxygen source for spontaneously breathing patients, because the resistance of the valves 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 Sotair device should be removed to allow the inspiratory resistance to be minimized.
- The Sotair device is compatible with the self-inflating type of manual resuscitators.
- Use the Sotair device with compatible manual resuscitator devices ONLY. Compatible devices are listed on Page 6.
- Do not use devices that are not compatible with the Sotair device. Using devices that are not compatible can cause undesirable increased resistance and dead space.
- The Sotair device increases inspiratory resistance by 1.5cmH_2O @ 50 LPM and expiratory resistance by 1.5cmH_2O @ 50 LPM. Do not attach the Sotair device if increased breathing resistance would be detrimental to the patient. If attached, remove the Sotair device if resuscitator function is degraded.
- The Sotair device adds a dead space of 15.9 ml to the manual resuscitator. Do not attach the Sotair device if increased dead space would be detrimental to the patient. If attached, remove the Sotair device if resuscitator function is degraded.

- Accessories to manual resuscitators may be used in series and can lead to undesirable increases in resistance and dead space. Other accessories like pop-off valves, PEEP valves, Impedance Threshold Devices, Colorimetric CO2 Detectors, $EtCO_2$ Capnography Sampling Lines do not affect the flow-limiting function of the Sotair device.
- Do not use the Sotair device in combination with devices other than a manual resuscitator and a mask interface if increased dead space or resistance would be detrimental to the patient.
- If the device has impaired function by vomitus, excessive blood or mucous, as determined by the user, discard the Sotair device and use a new Sotair device.



- **FORCEFUL SQUEEZE LIMITS FLOW and increases risk of hypoventilation.** When the user squeezes the bag forcefully generating a flow rate above 55 liters-per-minute (LPM), the Sotair limits flow. The device provides haptic, auditory, and visual feedback ONLY. It DOES NOT correct the flow by itself. To minimize the risk of hypoventilation, the user must adjust their ventilation technique and deliver breaths at flow rates less than approximately 55 LPM.
- Federal (U.S.A.) Law restricts this device to sale by or on the order of the physician.
- Do not use oxygen near flammable materials, smoke, fire, or other potential sources of combustion.

CAUTION:

- Do not attempt to attach the device to any connection or adaptor with incompatible sizing.

- Standard manual resuscitator functionality, including the ability to generate high flow rates, can be retained by removing the device.
- During chest compressions, backpressure felt on the bag may vary. User may need to adjust force applied to the bag in order to maintain desired flow rate.

INDICATIONS FOR USE:

The Sotair device is intended for use with a manual resuscitator with air-tight connections, in non-breathing patients that require flow controlled ventilation using ambient air or a supplemental oxygen source. The Sotair device is a single use, disposable device added to a manual resuscitator and can be used for in-hospital, emergency, and transport care. The adult Sotair device comprises a flow-limiting valve that limits the inspiratory flow enabling user to ventilate approximately 55 liters-per-minute (LPM). The flow-limiting valve is intended to minimize gastric inflation during manual ventilation. The Sotair device can be disabled by removing the device, thereby returning the manual resuscitator to its conventional operation. The Sotair device is for adult use only.

CONTRAINDICATIONS:

- When using a mask with the manual resuscitator, in scenarios where there is severe mask leakage.
- When there is a need for high-flow ventilation (approximately >60 LPM) as judged by the user.
- If the patient is breathing spontaneously, remove the Sotair.
- Do not use with other flow limiting devices.

PREPARATION:

1. Prior to use on patient, complete Steps 2 to 14.
2. Perform the functional test on the manual resuscitator according to the manufacturer's instructions for use.
3. Remove the Sotair device from the package.
4. Inspect for any damage.
5. If visible damage exists, discard and use another unit.
6. Perform the Sotair's brief functional test *(described in TEST OF FUNCTION Section, Page 3).*

TEST OF FUNCTION:

7. Connect the manual resuscitator's male connector (1) to the Sotair device's female portion (2) (**Figure A**).
8. Close / tighten all connections of the manual resuscitator and Sotair device.
9. Cover and occlude the male connector's opening (3) on the Sotair device with the palm of the hand (**Figure C**).
10. Briskly squeeze the bag while the palm of the hand is firmly covering the male connector's opening (3) on the Sotair device.
11. Ensure the bag does not deflate and resistance is felt when squeezing the bag (**Figure C**).

- If the bag is firm and/or no air is leaking from the bag, proceed to step 12.
- If the bag is deflating and/or air is leaking when squeezing the bag, then repeat steps 5 to 10 until all the connections of the Sotair device and manual resuscitator are secured and no air is leaking from the devices.
- If air continues to leak from the assembly, discard the Sotair device.

12. Remove palm of hand from the male connector's opening of the Sotair device.
13. Gently squeeze over 1-2 seconds and immediately release the bag.
14. Continue to squeeze and release the bag with increasing strength until the bag cannot be squeezed.
15. Confirm the valve is activated. This is the valve threshold (**Figure D**).

Note: The goal of the user is to ventilate the patient just below this threshold.

- Squeeze and release the manual resuscitator a few times to ensure that air is moving through the Sotair device and out of the male connector of the Sotair device (3) and that the valve system is functioning appropriately.
- Valve threshold activation will vary between patients and users

Figure A.

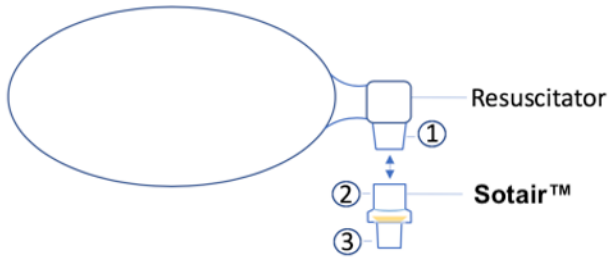


Figure B.

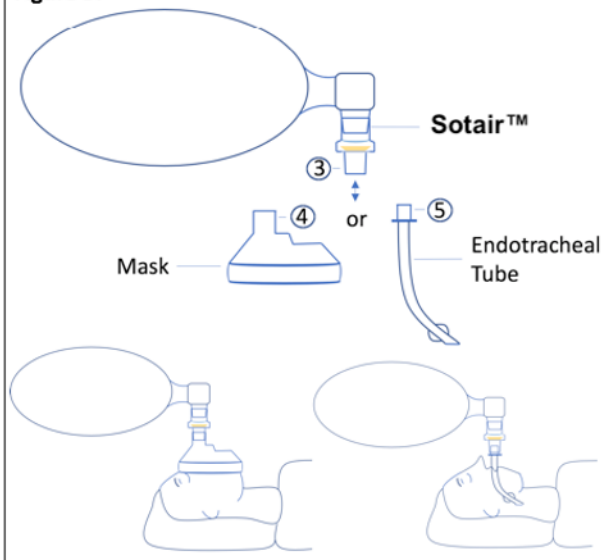


Figure C.

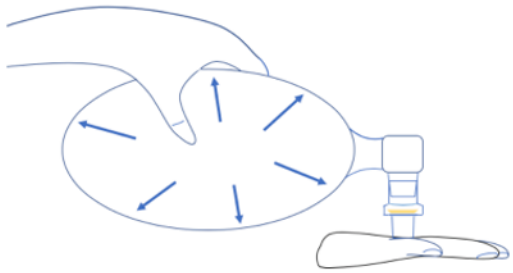
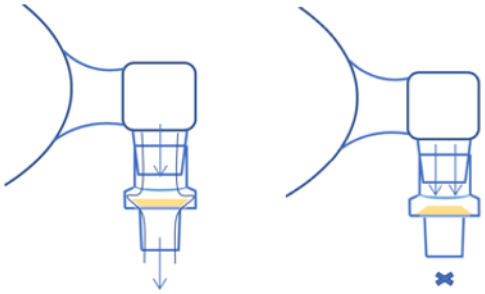


Figure D.



PATIENT USE:

16. Ensure the bag's male connector (1) is connected to the Sotair device's wider female connector (2) (**Figure A**).
17. Connect the Sotair device's male connector (3) to either a mask (4) or endotracheal tube (5) (**Figure B**).
18. Ventilate the patient in accordance with the manual resuscitator manufacturer's instructions for use.
    Warning: Do not ventilate over 55 LPM.
    Warning: Maintain good mask seal (if using mask).
19. Discarding the Sotair device should be conducted in accordance with local protocols.

TROUBLESHOOTING:

1. During ventilation, the user may occasionally reach the valve threshold, which causes the valve to close and the bag cannot be squeezed. This may happen in two situations: (a) User is delivering too much volume and/or (b) the user is squeezing the bag too quickly.
2. If the valve threshold is repeatedly reached (i.e., the valve is closed and the bag cannot be squeezed), the user should increase the time over which the breaths are being delivered and / or reduce the tidal volume by squeezing a smaller portion of the bag. The recommended squeeze time is between 1-2 seconds.
3. If an air leak or a defective valve is suspected, perform the *TEST OF FUNCTION* (page 3). If issues persist, discard the Sotair device.

SPECIFICATIONS*:

- PEEP: <0.5 cmH_20
- Permissible Flow rate: ~ $\leq$ 55 L/min
- Permissible Pressure: 10-22 cmH_2O
- Permissible Tidal Volume: 0-1000 ml
- Inspiratory time: 0.75 - 2.5 seconds
- Rise Time: N/A
- Expiratory Resistance: ~1.5cmH_2O @ 50 LPM
- Inspiratory Resistance: ~1.5cmH_2O @ 50 LPM
- Operating temperature: - 10ºC to +50ºC
- Operating Humidity: 15% - 95% rH
- Storage Temperature: -40 ºC to +60 ºC
- Storage Humidity: 40% - 95% rH
- Dead Space: 15.9 ml
- Adult Size: 5.715 cm long x 3.17 cm wide
- Adult Weight: 14 grams
- Diameter Connectors: Standard (15/22 mm connectors)
- Maximum Cycle Use: 10,000

*The specifications outlined above were developed using the Ambu SPUR II Adult Resuscitator, TSI 5300 SERIES MASS FLOW MULTI-METER, IMT Analytics AG CITREX H5 gas flow analyzer, and the IMT Analytics AG SL-2000-2L - Lung Simulator. Performance values provided are achievable under test conditions but may vary during actual use. Information on test methods is available from SafeBVM Corporation.

COMPATIBILE BAG RESUSCITATORS:

The Sotair device is compatible with all manual resuscitators and airway interfaces that have standard ISO 5356-1:2015 15/22 mm connections. The Sotair device's flow-limiting function has been tested with the following bag resuscitators:

Model Number	Description/Brand Name	Manufacturer
N/A	Adult Sotair™ Device	SafeBVM Corp.
520 211 00X, 520 211 00XX	Ambu Spur II, adult	Ambu
2442-BVMPAD	Curaplex Resuscitation Bags, adult premium BVM	Curaplex
301-558XEA	Curaplex® VentiSure2™ BVM Manual Resuscitator, Adult	Curaplex
04-2K80XX	AirLife Adult Manual Resuscitator	Vyaire Medical/Carefusion
AF5140MBX, AF5140MBXX	Sunmed/ventlab AirFlow Standard, Size 5	Sunmed/Ventlab
10564XX, 10585XX	Mercury Medical CPR 2 – Small Adult Bag	Mercury Medical
1056XXX. 10582XX	Adult CPR-2 Bag	Mercury Medical
850XX	1st Response Adult Manual Resuscitator with Oxygen Reservoir Bag	Smith's Medical
8451X1	The BAG II Resuscitator Adult w/ Mask #5	Laerdal
562013	Adult BagEasy Resuscitator w/ Mask	Westmed
L670-0X0XX	Disposable Bag Mask Resuscitator	Allied Healthcare Products
53710X	RUSCH, Manual Pulmonary Resuscitator with oxygen reservoir bag, Adult	Teleflex

NON-COMPATIBILE BAG RESUSCITATORS:

The Sotair device is not compatible with manual resuscitators that have a built-in flow limiting device such as the O-TWO SMART BAG MO.

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