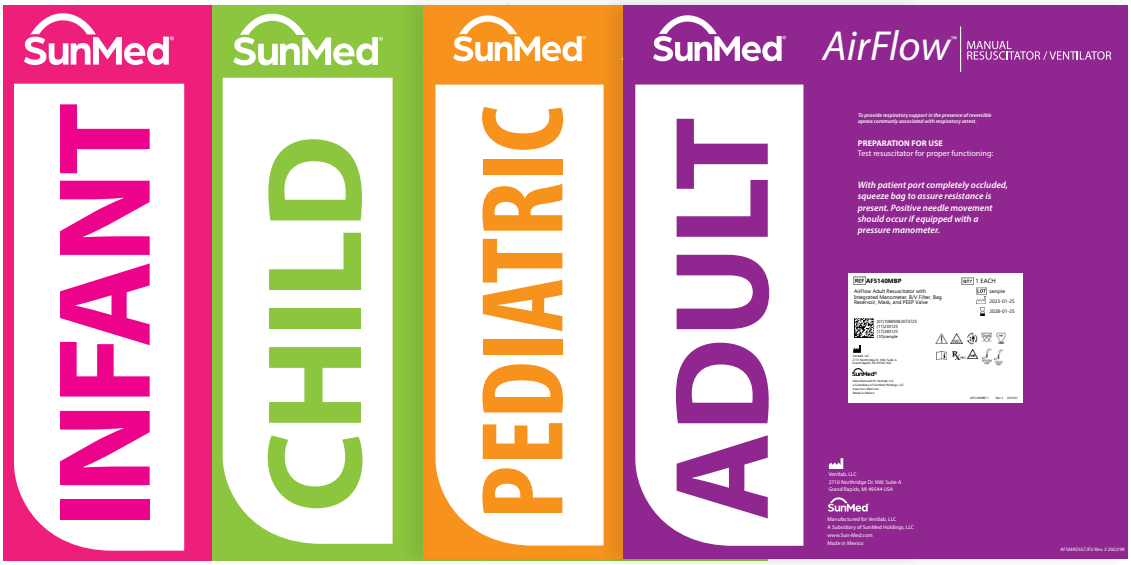
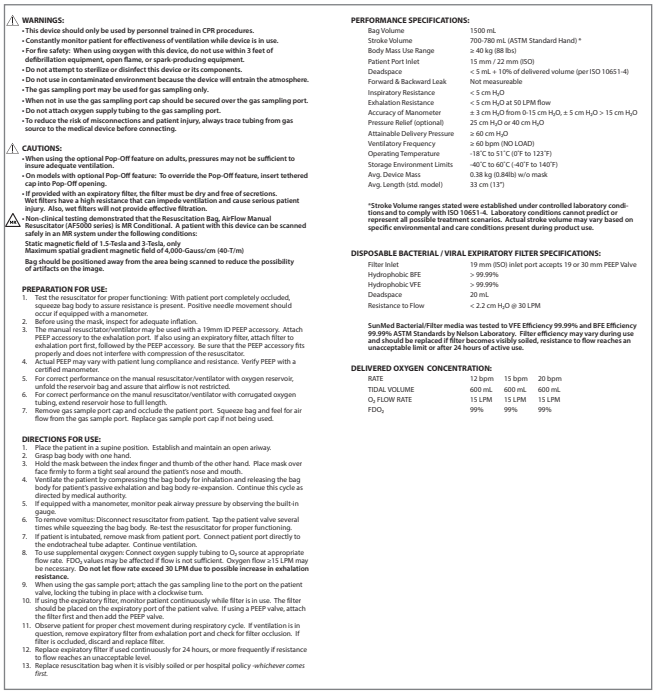
RESUSCITATION BAG HIGHLIGHTS

PACKAGING

Bag labels are color coded for easy identification



IFU and performance specifications printed on back of packaging



WARNINGS:

- This device should only be used by personnel trained in CPR procedures.
- Constantly monitor patient for effectiveness of ventilation while device is in use.
- For fire safety: When using oxygen with this device, do not use within 3 feet of defibrillation equipment, open flame, or spark-producing equipment.
- Do not attempt to sterilize or disinfect this device or its components.
- Do not use in contaminated environment because the device will entrain the atmosphere.
- The gas sampling port may be used for gas sampling only.
- When not in use the gas sampling port cap should be secured over the gas sampling port.
- Do not attach oxygen supply tubing to the gas sampling port.
- To reduce the risk of misconnections and patient injury, always trace tubing from gas source to the medical device before connecting.

CAUTIONS:

- When using the optional Pop-Off feature on adults, pressures may not be sufficient to insure adequate ventilation.
- On models with optional Pop-Off feature: To override the Pop-Off feature, insert tethered cap into Pop-Off opening.
- If provided with an expiratory filter, the filter must be dry and free of secretions. Wet filters have a high resistance that can impede ventilation and cause serious patient injury. Also, wet filters will not provide effective filtration.
- Non-clinical testing demonstrated that the Resuscitation Bag, AirFlow Manual Resuscitator (AFS000 series) is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:
  Static magnetic field of 1.5-Tesla and 3-Tesla, only
  Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
  Bag should be positioned away from the area being scanned to reduce the possibility of artifacts on the image.

PREPARATION FOR USE:

1. Test the resuscitator for proper functioning: With patient port completely occluded, squeeze bag body to assure resistance is present. Positive needle movement should occur if equipped with a manometer.
2. Before using the mask, inspect for adequate inflation.
3. The manual resuscitator/ventilator may be used with a 19mm ID PEEP accessory. Attach PEEP accessory to the exhalation port. If also using an expiratory filter, attach filter to exhalation port first, followed by the PEEP accessory. Be sure that the PEEP accessory fits properly and does not interfere with compression of the resuscitator.
4. Actual PEEP may vary with patient lung compliance and resistance. Verify PEEP with a certified manometer.
5. For correct performance on the manual resuscitator/ventilator with oxygen reservoir, unfold the reservoir bag and assure that airflow is not restricted.
6. For correct performance on the manul resuscitator/ventilator with corrugated oxygen tubing, extend reservoir hose to full length.
7. Remove gas sample port cap and occlude the patient port. Squeeze bag and feel for air flow from the gas sample port. Replace gas sample port cap if not being used.

DIRECTIONS FOR USE:

1. Place the patient in a supine position. Establish and maintain an open airway.
2. Grasp bag body with one hand.
3. Hold the mask between the index finger and thumb of the other hand. Place mask over face firmly to form a tight seal around the patient's nose and mouth.
4. Ventilate the patient by compressing the bag body for inhalation and releazing the bag body for patient's passive exhalation and bag body re-expansion. Continue this cycle as directed by medical authority.
5. If equipped with a manometer, monitor peak airway pressure by observing the built-in gauge.
6. To remove vomitus: Disconnect resuscitator from patient. Tap the patient valve several times while squeezing the bag body. Re-test the resuscitator for proper functioning.
7. If patient is intubated, remove mask from patient port. Connect patient port directly to the endotracheal tube adapter. Continue ventilation.
8. To use supplemental oxygen: Connect oxygen supply tubing to O_2 source at appropriate flow rate. FDO_2 values may be affected if flow is not sufficient. Oxygen flow ≥15 LPM may be necessary. **Do not let flow rate exceed 30 LPM due to possible increase in exhalation resistance.**
9. When using the gas sample port; attach the gas sampling line to the port on the patient valve, locking the tubing in place with a clockwise turn.
10. If using the expiratory filter, monitor patient continuously while filter is in use. The filter should be placed on the expiratory port of the patient valve. If using a PEEP valve, attach the filter first and then add the PEEP valve.
11. Observe patient for proper chest movement during respiratory cycle. If ventilation is in question, remove expiratory filter from exhalation port and check for filter occlusion. If filter is occluded, discard and replace filter.
12. Replace expiratory filter if used continuously for 24 hours, or more frequently if resistance to flow reaches an unacceptable level.
13. Replace resuscitation bag when it is visibly soiled or per hospital policy -*whichever comes first.*

PERFORMANCE SPECIFICATIONS:

Bag Volume	1500 mL
Stroke Volume	700-780 mL (ASTM Standard Hand) *
Body Mass Use Range	≥ 40 kg (88 lbs)
Patient Port Inlet	15 mm / 22 mm (ISO)
Deadspace	< 5 mL + 10% of delivered volume (per ISO 10651-4)
Forward & Backward Leak	Not measureable
Inspiratory Resistance	< 5 cm H_2O
Exhalation Resistance	< 5 cm H_2O at 50 LPM flow
Accuracy of Manometer	± 3 cm H_2O from 0-15 cm H_2O; ± 5 cm H_2O > 15 cm H_2O
Pressure Relief (optional)	25 cm H_2O or 40 cm H_2O
Attainable Delivery Pressure	≥ 60 cm H_2O
Ventilatory Frequency	≥ 60 bpm (NO LOAD)
Operating Temperature	-18°C to 51°C (0°F to 123°F)
Storage Environment Limits	-40°C to 60°C (-40°F to 140°F)
Avg. Device Mass	0.38 kg (0.84lb) w/o mask
Avg. Length (std. model)	33 cm (13")

*Stroke Volume ranges stated were established under controlled laboratory conditions and to comply with ISO 10651-4. Laboratory conditions cannot predict or represent all possible treatment scenarios. Actual stroke volume may vary based on specific environmental and care conditions present during product use.

DISPOSABLE BACTERIAL / VIRAL EXPIRATORY FILTER SPECIFICATIONS:

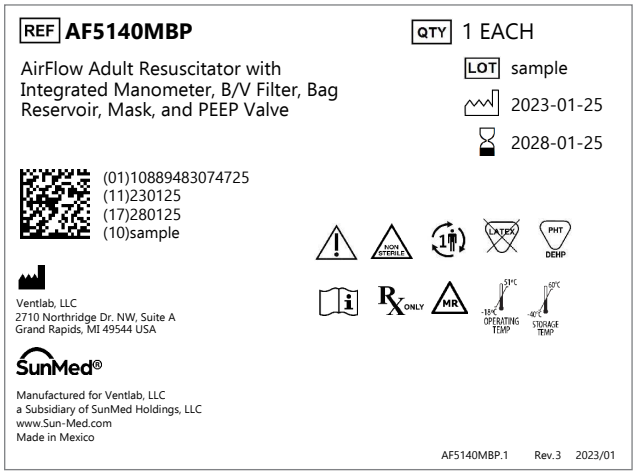
Filter Inlet	19 mm (ISO) inlet port accepts 19 or 30 mm PEEP Valve
Hydrophobic BFE	> 99.99%
Hydrophobic VFE	> 99.99%
Deadspace	20 mL
Resistance to Flow	< 2.2 cm H_2O @ 30 LPM

SunMed Bacterial/Filter media was tested to VFE Efficiency 99.99% and BFE Efficiency 99.99% ASTM Standards by Nelson Laboratory. Filter efficiency may vary during use and should be replaced if filter becomes visibly soiled, resistance to flow reaches an unacceptable limit or after 24 hours of active use.

DELIVERED OXYGEN CONCENTRATION:

RATE	12 bpm	15 bpm	20 bpm
TIDAL VOLUME	600 mL	600 mL	600 mL
O_2 FLOW RATE	15 LPM	15 LPM	15 LPM
FDO_2	99%	99%	99%

Bag part number clearly printed on front



REF **AF5140MBP**

AirFlow Adult Resuscitator with Integrated Manometer, B/V Filter, Bag Reservoir, Mask, and PEEP Valve

QTY 1 EACH

LOT sample

2023-01-25

2028-01-25

(01)10889483074725
(11)230125
(17)280125
(10)sample

NON STERILE · LATEX · PHT DEHP · Rx ONLY · MR · -18°C OPERATING TEMP · -40°C / -60°C STORAGE TEMP

Ventlab, LLC
2710 Northridge Dr. NW, Suite A
Grand Rapids, MI 49544 USA

SunMed®

Manufactured for Ventlab, LLC
a Subsidiary of SunMed Holdings, LLC
www.Sun-Med.com
Made in Mexico

AF5140MBP.1 Rev.3 2023/01

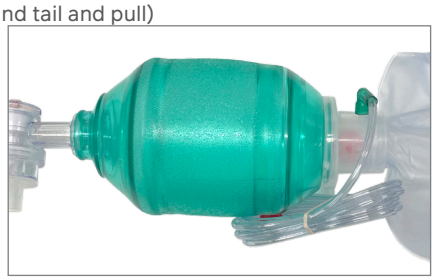
INSERVICE TOOL

AIRFLOW™ SIZE GUIDE

SIZE	LABEL COLOR	BODY MASS	BAG VOLUME	STROKE VOLUME
Infant	Pink	≤ 10 kg (22 lbs)	300 mL	150-170 mL
Child	Green	10 kg – 40 kg (22 lbs – 88 lbs)	550 mL	340-360 mL
Pediatric	Orange	≥ 25 kg (55 lbs)	1000 mL	590-600 mL
Adult	Purple	> 40 kg (88 lbs)	1500 mL	700-780 mL

BEFORE USE:

1. Verify red tape on the bag string is not broken or damaged before opening
2. The adult bags are packaged collapsed. After removing from the packaging, expand the bag to its full size (pinch at neck and tail and pull)

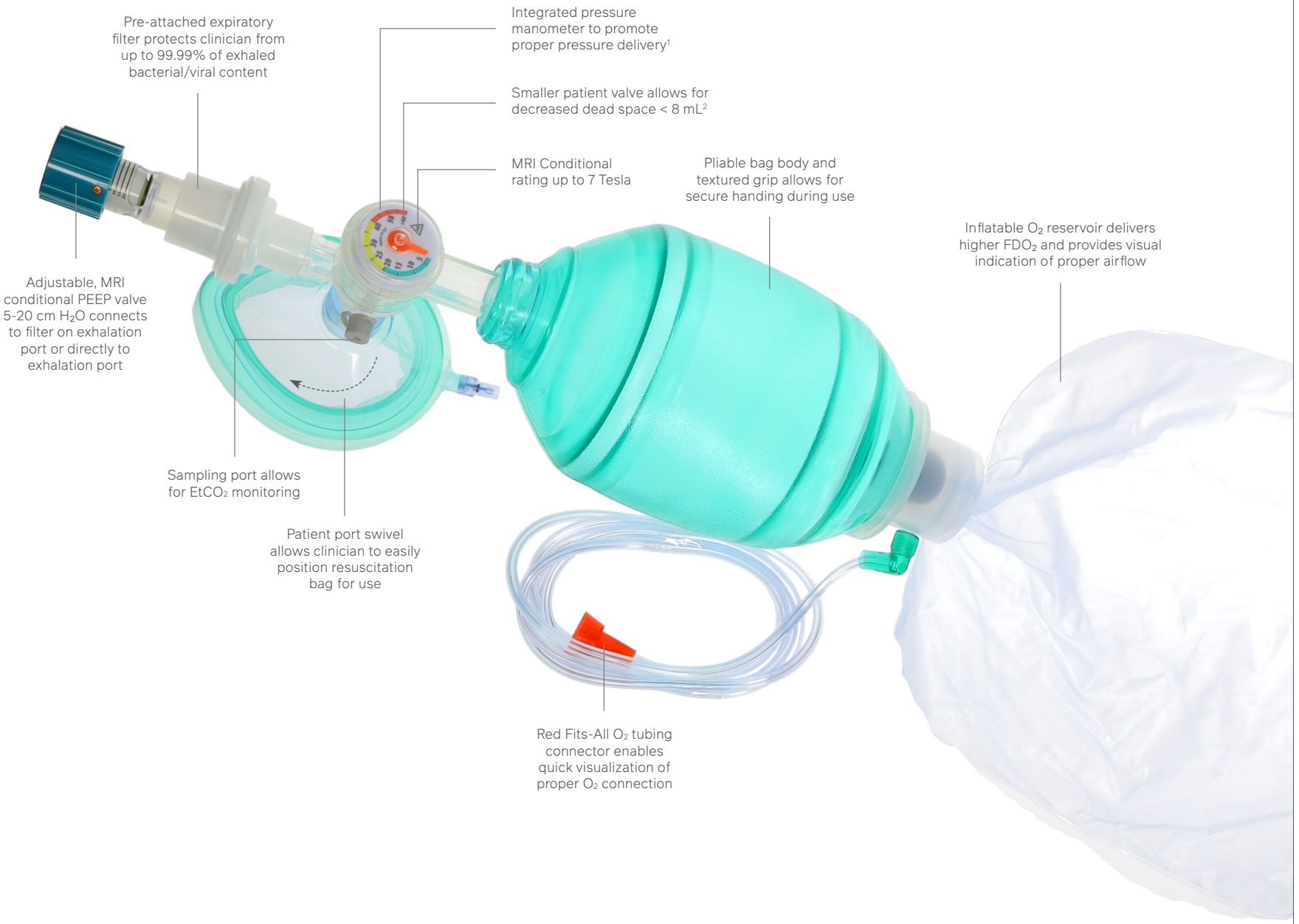


3. Occlude patient port and squeeze bag body to assure resistance and positive needle function on manometer
4. Inspect mask for adequate inflation
5. Attach PEEP to pre-attached B/V filter and confirm fit

6. Remove rubber band from 7' kink resistant oxygen tubing and unfold oxygen reservoir to assure airflow is not restricted

7. Connect red fits-all connector to oxygen and set flow to recommended flow rate
8. Follow Directions for Use

INSERVICE TOOL



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