

Safe Spot™ MANUAL RESUSCITATOR / VENTILATOR



To provide respiratory support in the presence of reversible apnea commonly associated with respiratory arrest.

PREPARATION FOR USE

Test resuscitator for proper functioning:

With patient port completely occluded, squeeze bag to ensure resistance is present. Positive needle movement should occur if equipped with a pressure manometer.

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.
- 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, pressure may not be sufficient to insure adequate ventilation.
- On models with option 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.

PREPARATION FOR USE

1. Test the resuscitator for proper functioning: With patient port completely occluded, squeeze bag body to ensure 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 19 mm ID PEEP accessory. Attach PEEP accessory to the exhalation port. Be sure that the 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 of the manual resuscitator/ventilator with oxygen reservoir, unfold the reservoir bag and assure that airflow is not restricted.
6. For correct performance of the manual resuscitator/ventilator with corrugated oxygen tubing, extend reservoir hose to full length.

DIRECTIONS FOR USE

1. Place the patient in a supine position. Establish and maintain an open airway.
2. Grasp the 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 releasing 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 O₂ source at appropriate flow rate. FDO₂ 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. 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.
10. 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.
11. Replace expiratory filter if used continuously for 24 hours, or more frequently if resistance to flow reaches an unacceptable level.
12. Replace resuscitation bag when it is visibly soiled or per hospital policy — whichever comes first.

PERFORMANCE SPECIFICATIONS

Bag Volume	300 mL
Stroke Volume	140-180 mL (ASTM Standard Hand)*
Body Mass Use Range	≤ 10 kg (22 lbs)
Patient Port Inlet	15 mm / 22 mm
Deadspace	≤ 5 mL + 10% of delivered volume (per ISO 10651-4)
Forward Leak	Not measurable
Backward Leak	Measurable
Inspiratory Resistance	<5 cm H ₂ O
Exhalation Resistance	<5 cm H ₂ O at 50 LPM flow
Accuracy of Manometer	± 5cm H ₂ O
Pressure Relief (optional)	25 cm H ₂ O or 40 cm H ₂ O
Attainable Delivery Pressure	≥ 80 cm H ₂ O
Ventilatory Frequency	≥ 90 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	0.20 kg (0.46 lb) w/o mask
Avg. Length (std. model)	22.5 cm (9")

* 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 the specific environmental and care conditions present during product use.

DISPOSABLE BACTERIAL / VIRAL EXPIRATORY FILTER SPECIFICATIONS

Filter Inlet	19mm (ISO) inlet port accepts 19 or 30mm PEEP Valve
Hydrophobic BFE	> 99.99%
Hydrophobic VFE	> 99.99%
Deadspace	20 mL
Resistance to Flow	< 2.2 cm H ₂ O @ 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	15 bpm	20 bpm	30 bpm
TIDAL VOLUME	150 mL	150 mL	150 mL
O ₂ FLOW RATE	10 LPM	10 LPM	10 LPM
FDO ₂	99%	99%	99%



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