

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 assure resistance is present. Positive needle movement should occur if equipped with a pressure manameter.

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.

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

- 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.
- 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.
- For correct performance on the manual resuscitator/ventilator with oxygen reservoir, unfold the reservoir bag and assure that airflow is not restricted.
- For correct performance on the manual resuscitator/ventilator with corrugated oxygen tubing, extend reservoir hose to full length.



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



Manufactured for Ventlab, LLC, a Subsidiary of SunMed Holdings, LLC www.Sun-Med.com Made in China by SunMed AP, LTD



MT Promedt Consulting GmbH Altenhofstrasse 80 66386 St. Ingbert Germany

Assembled and tested in U.S.A. with parts made in China SunMed is a registered trademark in the U.S.A.

((2797











DIRECTIONS FOR USE

- 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.
- If equipped with a manometer, monitor peak airway pressure by observing the built-in gauge.
- 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.
- 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.
- If using the expiratory filter, monitor patient continuously while filer is in use. Please observe patient for proper chest movement during respiratory cycle. If ventilation is in question, remove filter from exhalationport and check filter for occlusion. If filter is occluded, discard and change filter.
- 10. Replace expiratory filter if used continuously for 24 hours, or more frequently, if resistance to flow reaches unacceptable levels.
- Replace resuscitation bag when it is visibly soiled or per hospital policy — whichever comes first.

PERFORMANCE SPECIFICATIONS

Bag Volume 1500 mL

Stroke Volume 640-660 mL (ASTM Standard Hand)

Body Mass Use Range ≥40 kg (88 lbs) Patient Port Inlet 15 mm / 22 mm

Deadspace 10 mL with mask or low deadspace adapter

Forward & Backward Leak Not measurable Inspiratory Resistance <5 cm H₂O

Exhalation Resistance <5 cm H₂O at 50 lpm flow

Accuracy of Manometer ±5 cm H₂O

Pressure Relief (optional) 25 cm H₂O or 40 cm H₂O

Attainable Delivery Pressure ≥80 cm H₂O

Ventilatory Frequency

Operating Temperature

Storage Environment Limits

≥80 Ctm F20

≥60 bpm (NO LOAD)

-18°C to 51°C (0°F to 123°F)

-20°C to 60°C (-40°F to 140°F)

Avg. Device Mass 0.38 kg (0.84 lb) w/o mask

Avg. Length (std. model) 33 cm (13")

DISPOSABLE BACTERIAL/VIRAL EXPIRATORY FILTER SPECIFICATIONS

Filter Inlet 19 mm inlet port accepts 19 or 30 mm PEEP Valve

Hydrophobic BFE >99.99% Hydrophobic VFE >99.99% Deadspace 20 mL

 $Resistance \ to \ Flow \qquad <2.2 \ cm \ H_2O \ @ \ 30 \ lpm$

DELIVERED OXYGEN CONCENTRATION

RATE 12 bpm 15 bpm 20 bpm

TIDAL VOLUME 600 mL 600 mL 600 mL

O₂ FLOW RATE 15 lpm 15 lpm 15 lpm

FDO₂ 99% 99% 99% 99%

BVM500.INIFU Rev.2



1500 mL/BVM500 Series