ventlab
A SunMed Brand

INFANT

STAT-Check™ | MANUAL RESUSCITATOR / VENTILATOR

NON STERILE · LATEX · PHT DEHP · Rx ONLY

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 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.**

⚠ **When using manual resuscitators with an integrated manometer, the use of accessories (e.g., PEEP valve) on the exhalation port may increase the backward leak due to increased expiratory resistance. Monitoring of end tidal carbon dioxide is recommended in critically ill patients.**

⚠ **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

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 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 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 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 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. If using the expiratory filter, monitor patient continuously while filter is in use. Please observe patient for proper chest movement during respiratory cycle. If ventilation is in question, remove filter from exhalation port 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.
11. Replace resuscitation bag when it is visibly soiled or per hospital policy — *whichever comes first.*

PERFORMANCE SPECIFICATIONS

Bag Volume	300 mL
Stroke Volume	150-170 mL (ASTM Standard Hand)
Body Mass Use Range	≤10 kg (22 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 H_2O
Exhalation Resistance	<5 cm H_2O at 50 lpm flow
Accuracy of Manometer	±5 cm H_2O
Pressure Relief (optional)	25 cm H_2O or 40 cm H_2O
Attainable Delivery Pressure	≥80 cm H_2O
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")

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	<2.2 cm H_2O @ 30 lpm

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%

STAT-CHECK II CO_2 INDICATOR

This device is not a substitute for observation of the patient. The STAT-CHECK II must not be relied upon as the sole indicator of resuscitation effectiveness. This device is an indicator for both ventilation and circulation. The indicator should be checked frequently during use. Brain death occurs in 4-6 minutes without oxygenated blood flow. The signs of ventilation (i.e. Bilateral Breath Sound, "Fog-Sign", Observation of Chest and Abdomen etc.) and circulation (i.e. Carotid Pulse, Capillary Fill, etc.) must be monitored.

INDICATIONS FOR USE

The Stat-Check II is used as an adjunct assessment tool for verification of successful ventilation/intubation. Ventilation, intubation and circulation are confirmed by carefully watching for color change of the CO_2 indicator. The color of the indicator cartridge suggests the percentage of end-tidal CO_2 in the concentration range of 0 to 5%. The color of the cartridge may be compared to the label to give an approximation of end-tidal CO_2. Lack of color change may indicate improper intubation or no pulmonary perfusion.

PREPARATION FOR USE

1. Completely tighten the STAT-Check II indicator arm onto the threaded connection port by gripping the yellow labeled protective sleeve and turning clockwise.
2. Remove yellow labeled protective sleeve from indicator arm.

CAUTIONS

DO NOT ACTIVATE DEVICE UNTIL READY TO USE. Prolonged exposure to ambient air may yield erroneous results.

Gastric distention, vomitus and/or fluids or gasses that enter the side arm may cause color change independent of CO_2 concentration.

DIRECTIONS FOR USE

1. Begin ventilation efforts as directed by a medical authority.
2. Verify color change after 6 breaths (6 breaths will allow for washout of retained CO_2 in case of esophageal intubation).
3. In the presence of CO_2, the indicator cartridge should change from purple to tan or yellow based on the amount of CO_2 detected in the exhaled breath. Poor circulation can affect the amount of color change that takes place in the cartridge.
4. Subsequent color changes from purple to tan or yellow should be compared to label for an approximate assessment of end-tidal CO_2.

CO_2 INDICATOR SPECIFICATIONS

Expiration Date	See indicator arm or package label
Normal Usage	<4 hours
Optimal Storage Temperature	77°F (25°C)
For Use on Patients	>2.2 kg (5 lbs)

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