VT SELECT™

Pulmodyne®

Manual Resuscitator

INDICATIONS FOR MANUAL RESUSCITATOR USE:

- Pulmonary Resuscitation

CAUTIONS:

- This product must be used by qualified personnel in the techniques of pulmonary resuscitation.

WARNINGS:

- Never store this resuscitator in a compressed state other than as delivered by the manufacturer
- Verify pressure with a manometer at Manometer port.
- Do not occlude exit port of reservoir bag
- Resuscitators with PEEP valves should be used only qualified personnel.
- Device is packaged with the valve activated
- Always monitor the patient.
- Operating the resuscitator incorrectly can be hazardous
- Use the correct size resuscitator for the ideal body mass of the patient to avoid the risk of hypoventilation or barotrauma.
- Avoid using an oxygen concentration more than that which is clinically required by the patient. Delivering excessive oxygen can increase the risk of oxygen toxicity e.g. pulmonary damage, retinopathy of prematurity
- Patient expired gas is potentially infectious. Breathing filters can reduce but not eliminate contamination risk.

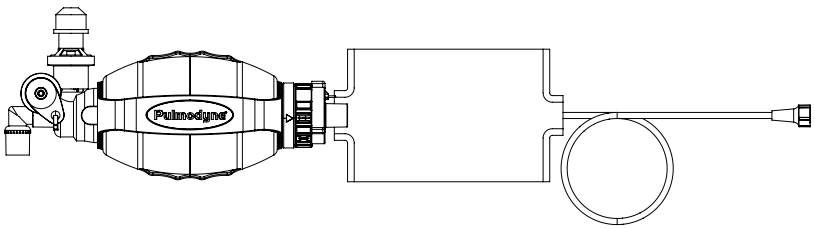
PRECAUTIONS:

DO:

1. Clear patient's airway before using manual resuscitator.
2. Always check for proper function of resuscitator:
   - Verify proper valve action.
   - Verify that the valve is free of obstruction
   - Verify patient is being ventilated by observing alternate rise and fall of the patient's chest and color of lips and face during resuscitation.

DO NOT:

1. Do not use in contaminated atomosphere (e.g., poisonous gases, smoke, etc.)
2. If oxygen is used, do not use in presence of sparking equipment or open flame.
3. Do not autoclave, gas, or chemically sterilize the Manual Resuscitator.
4. Do not lubricate fittings, connections, tubing, or other accessories of the resuscitator to avoid the risk of fire and burns.



DIRECTIONS FOR USE

Set-up of Manual Resuscitator

1. Prior to using the resuscitator, visually verify proper valve action while squeezing the resuscitator.
2. If resuscitating with high oxygen concentrations of oxygen, attach oxygen tube to proper oxygen source.
3. Set oxygen flow on the order of a physician. Do not exceed 15lpm.
4. To attach resuscitation bag to mask, press mask's 22mm I.D. into resuscutator's 22 O.D. connection.
5. When resuscitating through endotracheal tube or tube adapters, remove mask and attach 15mm O.D. tube adapter to resuscitator. This is a 15mm I.D. connection.

Operation of Manual Resuscitator-STANDARD SELECTION

1. Clear patient's airway, if obstructed.
2. Tilt patient's head back and pull chin up.
3. After establishing this position, place mask firmly over nose and mouth and hold in place.
4. Resuscitate patient by alternatively squeezing and releasing the bag at the prescribed rate.
   - If faster cycling at reduced FiO_2 is desired in the selected standard setting, unscrew tail end from the resuscitator to resuscitate without oxygen.
5. Verify that the patient's chest rises and falls during resuscitation. If movement is absent during resuscitation, check patient's airway.
6. Time manual resuscitation with any spontaneous breathing to prevent blockage of exhalation.
7. Clear valve obstructions, if any. Foreign material in the valve may be removed by squeezing the bag briskly and shaking any remaining obstruction of the exhalation port and/or rinsing with water.
8. Discard manual resuscitator after use

Operation of Manual Resuscitator-ACTIVATED SELECTION

1. Clear patient's airway, if obstructed.
2. Tilt patient's head back and pull chin up.
3. After establishing this position, place mask firmly over nose and mouth and hold in place.
4. Resuscitate patient by alternatively squeezing and releasing the bag.
5. When the activated valve is set, use one hand and place fingertips on the ridges of the bag. Optional strap is included to help hold the bag in place. when both the index finger and thumb come together. Wait until the bag fully inflates before beginning the next breath.
6. Verify that the patient's chest rises and falls during resuscitation. If movement is absent during resuscitation, check patient's airway.
7. Time manual resuscitation with any spontaneous breathing to prevent blockage of exhalation.
8. Clear valve obstructions, if any. Foreign material in the valve may be removed by squeezing the bag briskly and shaking any remaining obstruction of the exhalation port and/or rinsing with water.
9. Discard manual resuscitator after use.

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Made in Malaysia

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1 MD LATEX

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Resuscitator Specifications:	
Body Mass Range	>40kg (Adult)
Operating Environmental Limits	-18° C to 50°C
Storage Environmental Limits	-40° C to 60°C
Exhalation Port	30mm
Patient Connection	15mm I.D. x 22mm O.D.
Maximum Bag Volume	1200mL
Delivered Volume Range	(1 hand) 530mL (2 hand) 690mL
Deadspace (without mask)	9.6mL
Backward and Forward Leakage	Negligible
Expiratory Resistance	< 5 cm H_2O (0.5kPa) @ 50LPM
Inspiratory Resistance	< 5 cm H_2O (0.5kPa) @ 50LPM
Resuscitator External Dimensions	301mm length/116mm diameter
Resuscitator Mass (w/o mask)	373 g

SELECT VALVE POSITIONS:

STANDARD

ACTIVATED

STANDARD: The valve has no restriction and is acting as an unrestricted BVM.
ACTIVATED: The valve is restricted to produce a controlled tidal volume and timed refill.

INTENDED USE FOR ADJUSTABLE PEEP VALVE:

- The postive end expiratory pressure (PEEP) valve is designed to be used in conjunction with a manual resuscitation bag exhalation port to allow the user to select positive end expiratory pressure from 5 to 20cm H_2O. Attachment of this valve requires no modification to either the resuscitator or valve. If PEEP is not desired, remove PEEP valve.

CAUTIONS:

- This product must only be used by qualified personnel in the techniques of pulmonary resuscitation.
- During use, the patient's condition must be monitored.
- This product is not intended to be disassembled by the user; disassembly may result in improper valve function.

WARNINGS:

- PEEP may produce adverse effects. Close observation and reliable assessments are essential when using PEEP in patients with low circulatory blood volume, impaired cardiac function, bullous lung disease or higher than normal lung compliance. Assess the patient's hemodynamic, ventilatory, and oxygenation status whenever using PEEP.
- Use of sterilization or cleaning solutions may leave this product nonfunctional.
- This product is a one-way valve intended for respiratory use only and must not be used on anesthesia circuits.
- Do not use PEEP valve if it becomes occluded. An occluded PEEP valve obstruct patient's exhalation and result in potential injury. Remove valve from exhalation port and discard.
- Do not use PEEP unless you are qualified in the indications, benefits, side effects, contraindications, and goals of PEEP therapy.
- Do not use PEEP unless pressure is verified with a manometer.

DIRECTIONS FOR USE:

1. Prior to use, check to be sure the device is free of obstructions and verify proper valve function.
2. Firmly seat the valve onto the resuscitation bag exhalation port.
3. The valve is furnished with graduations at approximate PEEP levels of 5, 10, 15, and 20cm H2O. Using a manometer, verify PEEP settings prior to use.
4. Adjust the cap on the PEEP valve to acheive the desired PEEP levels. Clockwise rotation will increase PEEP levels.
5. Observe the position below cap of the indicator markings in relation to the pressure scale label to determine the approximate amount of PEEP being generated. Actual PEEP may vary with patient lung compliance and resistance. Verify pressure with a manometer.
6. If PEEP valve becomes occluded, remove from exhalation port and discard. A new PEEP valve can be readily attached to exhalation port.
7. Discard valve after use.

Delivered Oxygen Concentration (%) Average Values:			
Oxygen Flow Rate • Frequency (12 BPM) • Tidal Volume (600mL)	5	10	15
Oxygen Concentration:			
Standard	71	91	94
Activated	60	63	64

OPTIONAL ACCESSORIES:

- PEEP VALVE
- DISPOSABLE PRESSURE MANOMETER
- FILTER

INTENDED USE FOR DISPOSABLE PRESSURE MANOMETER:
To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port of proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP masks, or CPAP circuits.

INSTRUCTIONS:

1. Attach the manometer with its flexible connector onto the device's manometer port.
2. Occlude the patient port on the attached device and pressurize the manometer to maximum scale reading on the manometer.
3. Release the pressure and check that the float returns smoothly back to "0" cm H_2O mark.
4. Attach the system to the patient and monitor the patient to assure proper ventilation.
5. For a point of reference, set the "O" ring to be approximately at the desired pressure reading.
6. When repeated use is requiredfor the same patient, check the function and accuracy of the manmeter prior to each use.
7. Discard after use.

WARNINGS:

- For single patient use. Do not clean or sterilize as this may affect the accuracy or function of the manometer.
- Check function and accuracy prior to each use, including when repeated use is required for the same patient.
- A minimal amount of leakage of ariway gas is normal. The effects of this leakage must be evaluated for each patient.

CAUTIONS:

- This device must be used only by qualified personnel in the techniques of pulmonary resuscitationor airway management.
- During use, the patient's condition must be monitored. Should the performance of this device appear to be erratic during use, the device must be removed and replaced as required.

MANOMETER ACCURACY:
±1 cm H_2O from 0-10 cm H_2O
±2 cm H_2O from 10-40 cm H_2O
±3 cm H_2O from above 40 cm H_2O

INTENDED USE FOR FILTER (AERO-PRO COMPACT STRAIGHT):
This Depth Filter is designed for use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired.
Product Specifications and Information are listed in the table below.

Set Up:

1. Place the Filter in the circuit in the desired location, at the machine end, connected to the Inspiratory outlet and/or expiratory inlet, or between the artificial airway and the proximal breathing circuit.
2. Attach gas sampling line to luer port, if present.
3. Ensure connections are secure.
4. Check for airflow and function as part of circuit checkout procedure prior to use.

Cautions:

1. Do not resterilize, soak, rinse or reuse.
2. Ensure all connections are secure at all times.
3. Replace unit immediately if there is any contamination, occlusion or any indication of malfunction.
4. The dead space of this product should be taken into consideration when determining tidal volume and patient ventilation requirements.
5. Dispose of properly.
6. Federal (USA) law restricts this device to sale by or on the order of a physician.

Warnings:

- Replace Filter at least every 24 hours or earlier if increased resistance is noted.

Contraindications:

1. Filter should not be used in the proximal airway with patients producing fulminating frothy secretions within their airways, or patients with hemoptysis.
2. Do not use in conjunction with conventional humidifiers.
3. Do not add moisture to the Filter.
4. During delivery of inhaled medication the Filter should be removed or bypassed.

Product	Resistance to Flow (cmH2O @ L/min)	Dead Space (mL)	Weight (g)	Bacterial Efficiency	Viral Efficiency	Tidal Volume (mL)
Aero-Pro Compact Straight	2.0 @ 60	31.5	23.7	99.999	99.99	150-1000