CPR Bag

Reusable Manual Resuscitator

Mercury Medical

INDICATIONS FOR USE:

Provides emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

ACCESSORIES:

Disposable: Manometer, PEEP Valve, PEEP Adapter, OMNI-Link, Face Masks, Filter, Disconnect Wedge, Reservoir Bag, Oxygen Tubing
Reusable: Face Masks

WARNINGS:

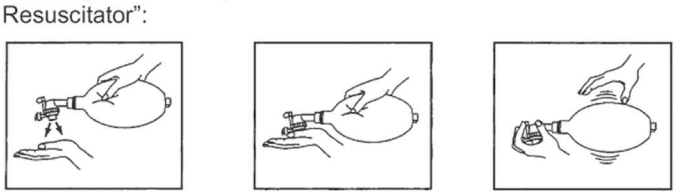
1. Incorrect operation of this device can be hazardous.
2. If used with supplemental oxygen, do not allow smoking or use unit near sparking equipment, open flame, oil or other flammable chemicals.
3. Should not be used in toxic or hazardous atmospheres.

PRECAUTIONS:

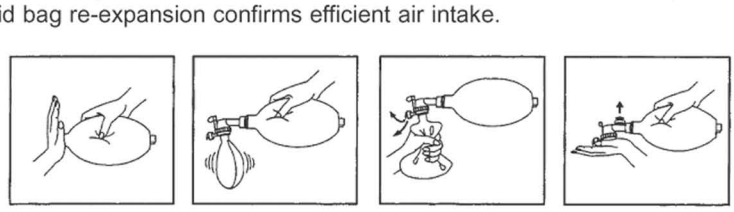
1. Resuscitator should be used only by personnel trained in cardiopulmonary resuscitation.
2. Never wait to begin mouth-to-mask resuscitation if a manual resuscitator is not immediately available or cannot be used effectively
   (see your department manual for accepted patient resuscitation procedure).
3. Infant and Child units are equipped with a pressure-limiting device which opens at approximately 40 cm H_2O. However, an abrupt, high-volume inspiratory delivery may cause the unit to exceed this level.
4. Verify proper function of the resuscitator and clear patient airway by monitoring for the following:
   - That the patient is being ventilated, as indicated by rise and fall of chest. The use of an airway pressure manometer is recommended.
   - Proper CPR Bag valve action (refer to "Test the Resuscitator" prior to using).
   - That the mask and valve are free from obstruction. To clear valve obstructions, squeeze and shake the bag briskly or rinse with water.
5. Do not attempt to autoclave the reservoir bag, oxygen tubing, optional disposable Positive End Expiratory Pressure (PEEP) valve or the disposable Pressure Manometer.

DIRECTIONS FOR USE:

1. Remove the resuscitator from the outer protective poly bag. Expand the CPR Bag to its operating position.
2. Inspect the unit to be sure the system is complete.
3. Prior to using; "Test the Resuscitator":



a) Compress the resuscitator bag with one hand, then occlude patient valve outlet with your other hand. Release the grip on the bag. Rapid bag re-expansion confirms efficient air intake.



b) Remove patient valve, close the neck opening and try to compress the bag. If the bag cannot be compressed with reasonable force, or if bag compression forces the air out between your hand and neck of the bag, the intake valve is efficiently preventing backward escape of air.

c) Attach the patient valve to the bag. Place a test lung over the valve connector (patient side). Test the resuscitator by squeezing and releasing the resuscitator bag with one hand as rapidly as possible for at least 10 breaths. Fully compress the resuscitator bag with each squeeze. This should fill the test lung and confirm that the patient valve efficiently directs inspiration air to the patient.

   Note: If the resuscitator continues to inflate because of the stacking of breaths, suspect a faulty patient valve and remove the resuscitator from service.

d) Compress the filled test lung. Air should vent to the atmosphere and not return to the ventilation bag.

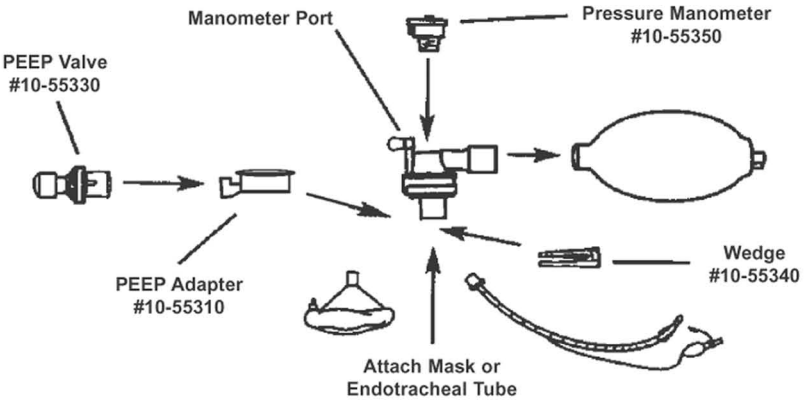
e) When using unit with a pressure-limiting device, test for proper function by occluding patient valve outlet and compressing the bag to verify opening of the pressure-limiting device.

   Note: If the resuscitator does not pass all criteria as described under "Test the Resuscitator", take immediate action by replacing resuscitator.

4. INSPIRATION PRESSURE-LIMITING DEVICE. The infant and child resuscitators may feature a patient valve with a special pressure-limiting device mounted on the upper valve housing. If inspiration meets with pulmonary resistance, venting will occur, limiting pressure to 40 +5/-10 cm H_2O, thereby reducing the risk of stomach distension. A hissing sound can be heard as the device opens. The patient valve provides a built-in port for pressure monitoring, recommended when resuscitating infants and small children, remove the cap and attach your monitoring device, re-attach cap when not using.

   Note: When higher inspiration pressures are necessary, the pressure-limiting device can be closed with the tip of the index finger or by engaging the lock-out clip while squeezing the bag. The use of an airway pressure manometer is recommended when doing this procedure.

5. If resuscitating where high concentrations of oxygen are needed, attach oxygen tubing adapter to proper oxygen source, such as a flow meter or adjustable oxygen regulator.
6. PEEP Valve may be attached using MERCURY MEDICAL® PEEP Valve Adapter. When adjusting the MERCURY MEDICAL® PEEP Valve, connect a manometer in-line with the patient breathing system and read the manometer during adjustment. Rotate adjustment cap clockwise to increase PEEP or counterclockwise to decrease PEEP. The adjustment range is 0 - 20 cm H_2O (mbar).



OPERATING INSTRUCTIONS:

a. Clear mouth of foreign matter.

b. Position patient for open airway.

c. Apply mask firmly to face to achieve a tight seal. If patient is intubated, attach the patient valve connector to the tube adapter.

d. Squeeze and release bag quickly, allowing enough time between inspirations for the patient to exhale and the bag to re-expand.

e. Observe rise and fall of patient's chest and listen for air flow from patient valve as patient exhales.

Note: If these do not occur, patient's airway or patient valve may be blocked. Take immediate action by replacing the resuscitator or use an alternative procedure appropriate for situation.

CLEANING & STERILIZATION INSTRUCTIONS:

The Mercury Medical Reusable Resuscitation system is designed to be fully autoclavable, with the exception of certain accessories and replacement items, such as the Reservoir Bag, Oxygen Tubing, OMNI-Link, Filter, Disconnect Wedge, optional Positive End Expiratory Pressure (PEEP) Valve and PEEP Adapter, and the Pressure Manometer.

CLEANING

Prior to sterilization the autoclavable portion of the device must be cleaned of all debris, bodily fluids and other contaminants.

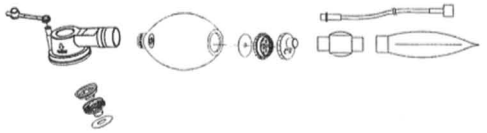
1. Remove non-autoclavable items and discard them.
2. Disassemble the device as shown in Figure below.
3. Disassemble the patient valve as shown in Figure below.
4. Thoroughly rinse the device in warm water (less than 100° F/38° C).
5. Using a compatible enzymatic detergent, thoroughly clean the device using a soft brush paying particular attention to the inner surfaces of air pathway.
6. Rinse all parts thoroughly with warm water. Brush with a clean, soft brush as necessary. Ensure that the detergent has been rinsed from the device.
7. All parts must be rinsed free of any residue, contaminant or detergent. Inspect the device carefully after rinsing. If residue cannot be removed by repeated cleaning, discard the component affected and replace the component.

Note: Failure to thoroughly clean the device may result in device malfunction.

STERILIZATION

1. The device must be thoroughly cleaned prior to sterilization.
2. The device is designed to be sterilized by moist heat (autoclave). Other methods of sterilization or high level disinfection should NOT be utilized.
3. The autoclave cycle utilized should be validated in accordance with accepted standards, such as ANSI/AAMI ST46:2002, "steam sterilization and sterility assurance in health care facilities" and ISO 13683 "Sterilization of health care products - Requirements for validation and routine control of moist heat sterilization in health care facilities."
4. Recommended Cycle: Vacuum cycle at 132 °C (270 °F) for 3 minutes. The device must be processed in a validated sterilization cycle. Refer to the manufacturers' recommendations supplied with the autoclave.
5. Allow all parts to cool and air dry prior to reassembly.
6. Prior to assembly, inspect the device components for signs of damage or excessive wear. Replace worn or damaged components.
7. Carefully assemble the device, refer to Figure below. When reassembling the patient valve, ensure the valve components are oriented properly and securely connected (see Figure below). Replace the Pressure Manometer (optional).
8. Test the Resuscitator as described in "Directions for Use," (Step 3).

Assembly/Disassembly
Adult Device w/ Patient Valve

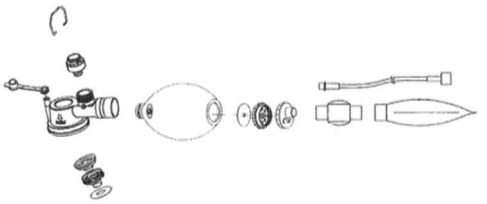


Adult
Patient Valve Assembly

Adult
Bag Assembly

Oxygen Valve;
Reservoir and Tubing

Assembly/Disassembly
Child/Infant Device w/ Patient Valve



Child/Infant
Patient Valve Assembly

Child/Infant
Bag Assembly

Oxygen Valve;
Reservoir and Tubing

SPECIFICATIONS AND PERFORMANCE*:

The MERCURY MEDICAL® CPR Bag was designed to meet ISO 10651-4 and ISO 5356-1 requirements.

OXYGEN CONCENTRATION:

	LPM	Rate	Tidal Volume	w/Reservoir	w/o Reservoir
Adult:	10	12	500 ml	100%	52%
Child:	10	20	250 ml	100%	60%
Infant:	4	30	40 ml	100%	68%

MAXIMUM STROKE VOLUME:

	One Hand	Two Hands
Adult	1150 ml	1460 ml
Child	420 ml	n/a
Infant	220 ml	n/a

PATIENT BODY MASS RECOMMENDATIONS:

Adult	Over 20 Kg
Child	10 - 20 Kg
Infant	Under 10 Kg

RESUSCITATOR MASS:
(Patient valve and bag only)

Adult	335 grams
Child	202 grams
Infant	165 grams

The correct ventilation frequency may vary. Please follow the current ventilation frequency recommended by the AHA.

EXTERNAL RESUSCITATOR DIMENSIONS
(Patient valve and bag only):

Adult	32 cm long x 14 cm diameter
Child	25 cm long x 9 cm diameter
Infant	24 cm long x 7 cm diameter

MEASURED VOLUME:

	Bag	Reservoir
Adult	1624 ml	2854 ml
Child	494 ml	2854 ml
Infant	246 ml	692 ml

EXPIRATORY RESISTANCE: 2.5 cm H_2O @ 50 LPM

INSPIRATORY RESISTANCE: < 5 cm H_2O @ 50 LPM

OXYGEN TUBING CONNECTION: Universal adapter fits C.G.A. D.I.S.S. 1240 or .250 inch hose barb.

IMPACT TEST: The Mercury Medical® CPR Bag showed no signs of damage or degradation of performance as a result of a one meter drop onto a concrete surface.

OPERATING ENVIRONMENTAL LIMITS: -18° to +50° C

STORAGE ENVIRONMENTAL LIMITS: -40° to +60° C

DEAD SPACE: 7 ml

*Performance values given are achievable under test conditions but may vary during actual use.
Information on test methods is available from MERCURY MEDICAL®.

The CPR Bag is manufactured, approved, sponsored and endorsed by MERCURY MEDICAL® and has no connection with the Laerdal Medical Corporation.

Mercury Medical

EC REP

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The Netherlands

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By Prescription Only

LATEX
Latex Free

NON STERILE
Non Sterile

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Additional copies of the "CPR Bag Directions for Use" are available on request. Contact the Marketing Dept. at 800-237-6418

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