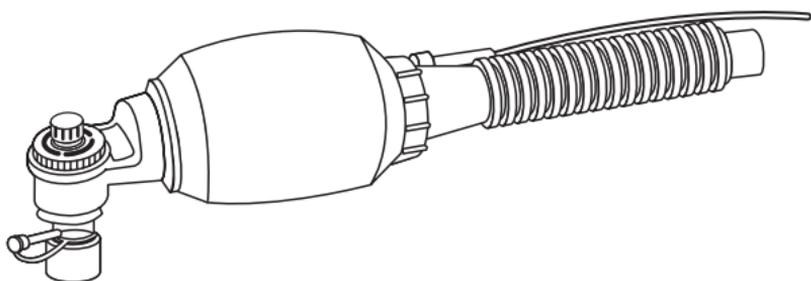


Infant PMR 2 Resuscitator

Operating Instructions



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Latex Free

STERILE EO

Rx ONLY

Directions for Use

The Reusable Manual Resuscitator (PMR[®] 2) is a bag-valve-mask device with the capability of delivering supplemental oxygen. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen enriched air with the attachment of an oxygen accumulator when a supplemental oxygen source is available. The PMR 2 is not recommended for use in contaminated atmospheres as ambient air can be drawn into the bag and inhaled by the patient.

Reference: Standards for Cardiopulmonary Resuscitation (CPR) as defined by the *Journal of the American Medical Association*.

CAUTION:

- This product is intended for use by personnel who are thoroughly trained in the physiology and techniques of cardiopulmonary resuscitation.

WARNING:

- **No smoking, naked flames or sources of ignition.**
- **Use may be hazardous in toxic environments unless entrainment is prevented.**
- **Before using the resuscitator on a patient, perform a functional check.**
- **After cleaning and sterilization, or extended periods of storage, and prior to placing in service the following functional tests should be performed.**

General Check

Squeeze and release the resuscitator bag and observe that the air flows out the patient port and that the fill valve permits air to refill the bag rapidly (repeat the check several times).

To Check Fill Valve and Nonbreathing Valve

Attach a test lung to the resuscitator patient connection. Squeeze and release the bag several times. The test lung should inflate during the squeeze and deflate when the bag is released. The bag should refill rapidly.

If the Bag Does Not Refill

Verify that the check valve is functioning properly. Be certain only one check valve is installed.

If the Test Lung Does Not Deflate

Check the nonbreathing valve to be certain that there is only one diaphragm in place and that it moves freely within the housing.

If the Test Lung Does Not Inflate

Check bag connections and valve components for leaks (refer to the sections titled To Check the Relief Valve and To Check for Leaks).

To Check the Relief Valve

Turn the valve poppet to the ON position. Occlude the patient connection. Briskly squeeze the bag. The poppet should open allowing excess pressure to escape.

To Check for Leaks

Turn the relief valve poppet to the OFF position. Occlude the patient connection. Briskly squeeze the bag, holding the squeeze. The resuscitator should offer resistance to the squeeze. Observe a small leak as the bag is squeezed slowly. This leak is necessary for proper function of the resuscitator.

If the Bag Will Not Hold Air When Squeezed Briskly

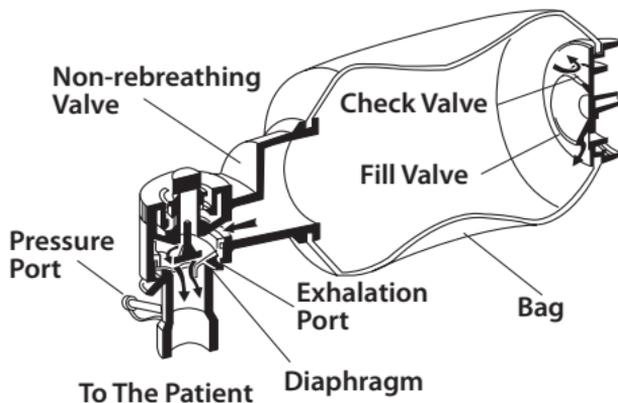
Remove the fill valve and observe that the check valve is positioned properly as shown in Figure 11. Inspect the nonbreathing valve to determine that all parts are in place as shown in Figure 9. Check the bag seal as shown in Figure 10. Check to be certain the cap on the nonbreathing valve is screwed on fully to prevent leakage. If the relief valve leaks in the OFF position (black band showing), check to be certain the poppet has been fully turned until it stops. Be certain the pressure port cap is in place.

Inflation

When the resuscitator bag is squeezed, air is forced from the bag and flows out through the opening in the center of the nonbreathing valve diaphragm and into the mask, infant's airway, and lungs. Pressure generated by the bag-squeeze forces the outer edge of the diaphragm against the exhalation port seal to prevent leaking (Figure 1).

A check valve prevents air from escaping through the fill valve when the bag is squeezed.

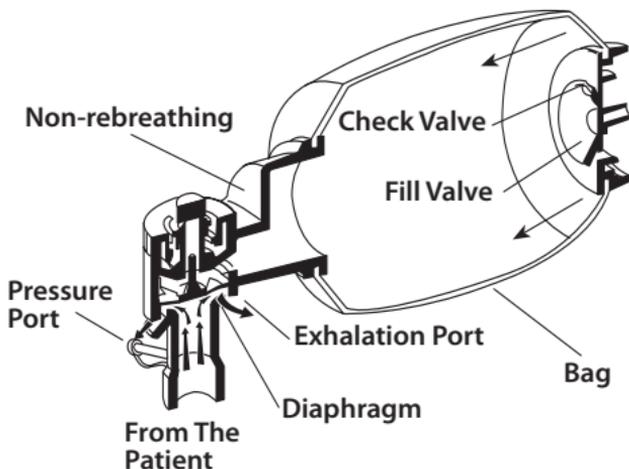
Figure 1



Exhalation

During exhalation, the nonbreathing valve diaphragm lifts from the exhalation port seal and air is expelled from the ports. The opening in the center of the nonbreathing valve diaphragm is closed by a seat on the valve cage, to prevent expelled air from entering the bag. The check valve on the fill valve opens allowing air to re-enter and refill the bag (Figure 2).

Figure 2



WARNING:

- **A self-inflating resuscitator such as the PMR 2 will not deliver free-flow oxygen through the nonbreathing valve. If oxygen tubing has been connected to the fill valve portion of the resuscitator, it may be disconnected and used to direct free-flow oxygen.**

Spontaneous Breathing

Should the infant resume breathing, free-flow oxygen may be provided by holding the end of an oxygen supply tube over the infant's nose and directing oxygen using clinically accepted technique.

Using the PMR 2 with Supplemental Oxygen

When available, supplemental oxygen can be added to enrich the air delivered by the resuscitator. Two methods may be employed to provide supplemental oxygen. To provide supplemental oxygen, the fill valve cap must be attached to the resuscitator.

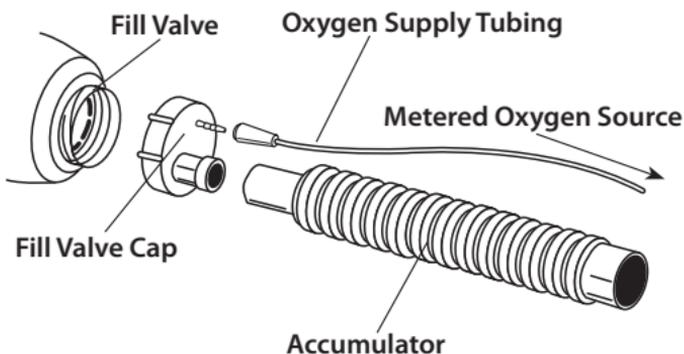
1. **Using the Oxygen Accumulator:** An accumulator can be attached to the fill valve cap to provide higher concentrations of oxygen. The accumulator serves as a reservoir to store oxygen while the bag is squeezed. When the bag is released, stored oxygen is drawn from the accumulator into the bag.

Achievable oxygen concentration is influenced by the oxygen flow and bag refill time. Slowing the bag refill time permits more oxygen to be drawn into the bag resulting in a higher concentration.

- a. Attach the accumulator to the large connection on the fill valve cap.

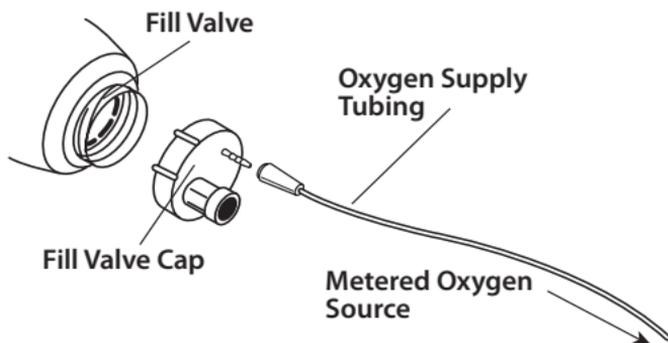
- b. Connect tubing (3/16" to 1/4" ID) from a regulated and metered oxygen source (flowmeter) to the tubing connection marked OXYGEN INLET on the fill valve cap (Figure 3).
- c. Set the oxygen flow rate at the desired value and begin resuscitation.

Figure 3



2. Using Oxygen at the Fill Valve: In the event an oxygen accumulator is not available.
 - a. Connect 3/16" or 1/4" ID tubing from a regulated and metered oxygen source (flowmeter) to the tubing connection marked OXYGEN INLET on the fill valve cap (Figure 4).
 - b. Set the oxygen flow rate at the desired value and begin resuscitation.

Figure 4



WARNINGS:

- **Oxygen, while not flammable, supports combustion. Do not use oil or grease on oxygen cylinders, valves, or equipment. Do not use or store cylinders near excessive heat, 54°F (130°C) or open flame.**
- **Avoid using flowmeter at flush settings or delivery flows in excess of 30 lpm. This may result in increased resistance to exhalation of 2 to 3 cmH₂O.**
- **The infant resuscitator will not accept or function with oxygen supply valves. Do not attempt to insert the bag fill housing from the larger child or adult PMR 2 resuscitator.**

Relief Valve Operation

The relief valve will open if airway pressure exceeds 40 cmH₂O \pm 5 cmH₂O with a flow of 15 lpm through the relief valve.

The pressure in the airway system when the relief valve is operational will depend on:

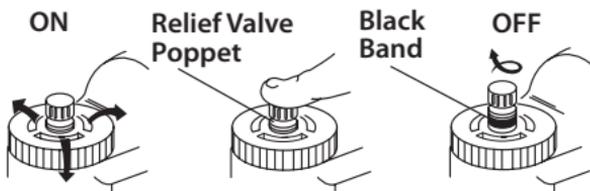
- rate of bag squeeze
- volume of air produced by the squeeze
- resistance and compliance of the pulmonary system

If desired, the relief valve function may be temporarily overridden by placing a finger on the valve poppet to prevent it from lifting (Figure 5).

When difficulty is experienced in delivery of required volumes to the patient, the relief valve function may be overridden. Delivery pressures must be monitored by a pressure gauge or manometer connected to the pressure port.

The relief valve function may be canceled by lifting and rotating the poppet clockwise until it stops. The black band will be showing (Figure 5).

Figure 5



WARNING:

- **A No Pressure Relief cap, available for use with the two larger PMR 2 resuscitators, is NOT recommended for use with the infant model as excessive pressures during inflation of the lungs may occur.**

Positive End Expiratory Pressure (PEEP)

A reusable PEEP accessory is available for use when positive end expiratory pressure is desired. Refer to Operating and Maintenance Instructions (P/N 847510-00) provided with the PEEP accessory.

WARNING:

- **The relief valve cap, valve cage, and red diaphragm must be removed from the non-rebreathing valve body before installing the PEEP accessory or the accessory and resuscitator will not function (Figure 6).**

Using the Pressure Port

The resuscitator is provided with a patient pressure port as a part of the non-rebreathing valve (Figure 7). The pressure port is used for connection to a pressure manometer or pressure gauge. A cap is provided to prevent leakage when the pressure port is not used. For use of a gauge or manometer, provide tubing with an ID of 3/16" or 1/4" and follow the instructions provided by the manufacturer.

Figure 6

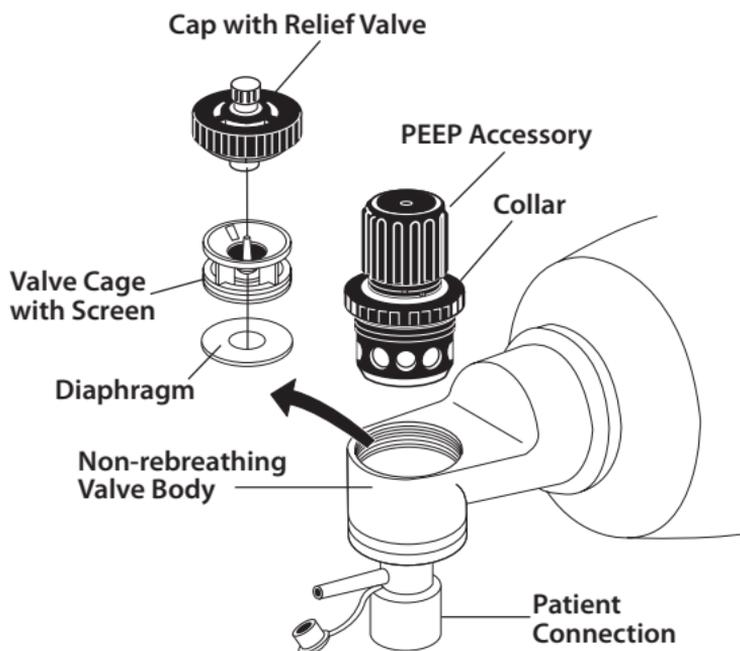
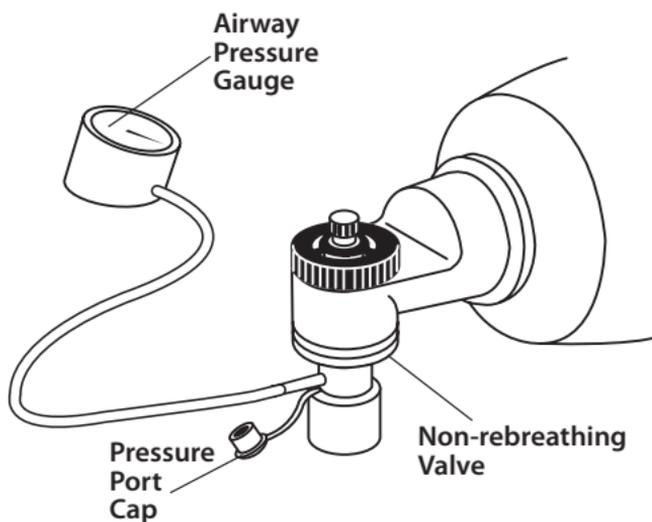


Figure 7



WARNING:

- Do not use the pressure port to provide the infant with supplemental oxygen. An oxygen connection is provided on the fill valve cap. Refer to the section on Using the PMR 2 with Supplemental Oxygen, page 4.

Artificial Ventilation

Use accepted procedures for positioning the infant and establishing an open airway.

WARNING:

- **Before using the resuscitator on a patient, perform a functional check.**

Fitting the Mask

Choose a mask which will fit the infant and attach it to the resuscitator. Position the mask on the infant using a light downward pressure to achieve and maintain an air-tight seal (Figure 8).

Figure 8



Inflating the Lungs

Ventilate the infant by rhythmically compressing the bag for inhalation and releasing for exhalation and refilling of the bag.

Continued Ventilation

Ventilation should continue according to established standards and recommendations for cardiopulmonary resuscitation until the infant is breathing on its own or medical authority on the scene advises to cease.

Clearing the Resuscitator Valve

If the resuscitator becomes obstructed:

1. Vigorously shake or strike the patient connection with a hand to dislodge any obstruction.

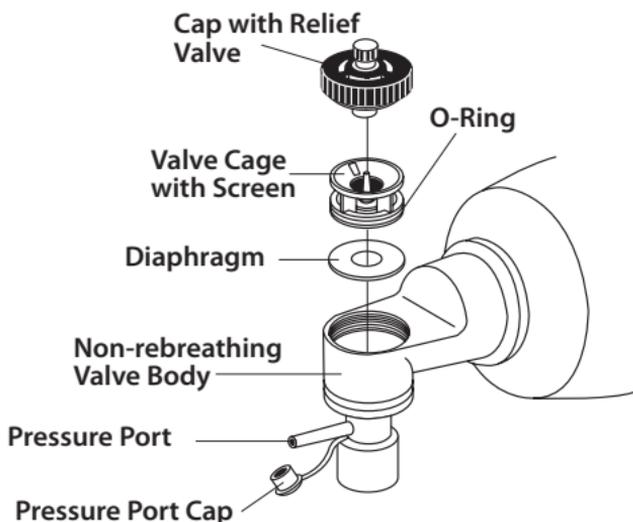
If the valve remains obstructed:

2. Remove the relief valve/cap assembly, valve cage, and diaphragm and shake, wipe, or rinse clean and reassemble to continue ventilation (Figure 9).

Note:

- Removal of material from the pressure port is very important as the small internal passage can easily become occluded. Use a cleaning wire to be certain the port is open.

Figure 9



Cleaning and Sterilization

The resuscitator must be completely disassembled before cleaning and sterilization.

Materials used in the resuscitator are identified in the parts list on page 14. These materials are selected to meet resuscitator functional requirements and provide strength and durability. Most common cleaning, disinfecting, and sterilization methods can be used provided procedures and chemicals selected are compatible with product materials.

To prolong the life of the resuscitator, the following precautions are recommended as a result of testing and experience.

Detergents

Follow the detergent manufacturer's instructions. Rinse parts thoroughly to remove all detergent residue. Wipe parts dry. Detergent residue can cause blemishes, especially on parts exposed to elevated temperatures during sterilization.

CAUTION:

- Exposure to detergent solutions stronger than necessary may shorten the useful life of the product.

Chemical Disinfectants

An aqueous-activated glutaraldehyde disinfectant solution is recommended. When using any other type of disinfectant, consult the manufacturer's instructions for material compatibility or evaluate its suitability on a selected part. Formaldehyde and phenol-based solutions are not recommended as these agents can cause cracking and crazing of plastic parts. Parts should be thoroughly rinsed and dried to prevent blemishes when exposed to elevated temperatures when sterilized.

CAUTION:

- Exposure of components to disinfectant concentrations stronger than required or for an excessive time may shorten product life.

Steam Autoclaving

All parts of the resuscitator may be steam autoclaved. A cycle of three to five minutes at 270°F (132°C) is recommended. Disassemble the resuscitator before autoclaving. Heavy parts resting on the bag may cause permanent distortion.

CAUTIONS:

- The relief valve cap must be removed from the non-rebreathing valve housing and the fill valve cap must be removed from the fill valve to prevent distortion during autoclaving.
- Autoclave temperatures in excess of 270 °F can cause distortion and dimensional changes in plastic parts, embrittlement of rubber parts and reduced product life. Periodically monitor autoclave temperatures.

Gas-Vacuum Sterilization

All parts of the resuscitator may be gas sterilized. Ensure that the resuscitator has been disassembled and cleaned. Wrap components in packaging suitable for ETO sterilization. Expose to the gas sterilization cycle recommended by the sterilizer manufacturer and validated by your health care institution to ensure sterility. Degas in an ETO aerator for a time and at a temperature recommended by the aerator manufacturer and validated by your institution to ensure elimination of residual ETO.

WARNING:

- **After cleaning and sterilization, assemble the resuscitator and test for proper operation before returning it for use.**

Storage

The resuscitator may be stored in the carrying case or a plastic bag to prevent accumulation of dust. Do not compress the bag during long periods of storage and observe temperature ranges of -40° to 140°F (-40° to 60°C). When placing the resuscitator into service after any period of storage, perform a functional operation check.

Maintenance

After each use, disassemble the resuscitator, wash, disinfect, and replace damaged parts as necessary.

To Disassemble the Resuscitator:

1. Disassemble the non-rebreathing valve by removing the cap, pressure port cap, cage, O-ring seal, and diaphragm. Do not attempt to remove the screen from the valve cage (Figure 10).
2. Remove the non-rebreathing valve body and fill valve from the bag. Grasp the bag near the part to be removed and pull the bag away from the sealing groove. To facilitate removal and installation of the fill valve, connect it to the fill valve cap which provides a larger surface to grip (Figure 11).

CAUTION:

- The bag is made of silicone rubber which has excellent resistance to aging and temperature extremes but can easily be damaged by cuts. Do not use any instruments to pry on either the non-rebreathing valve or fill valve when removing or installing. Tears to the bag will result if instruments are used. The correct method is given in this instruction and shown in (figure 11).
3. Remove the check valve from the fill valve by gently pulling over the collar beginning at the cut-away portion (Figure 10).

Figure 10

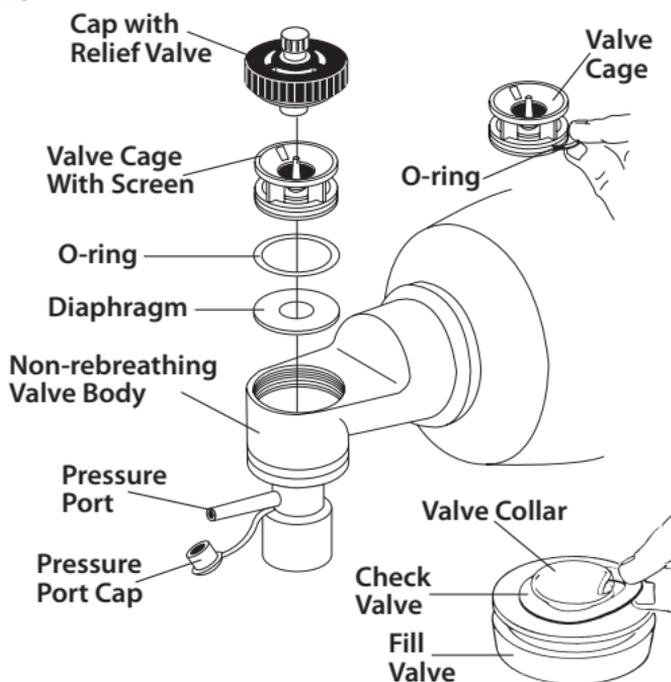
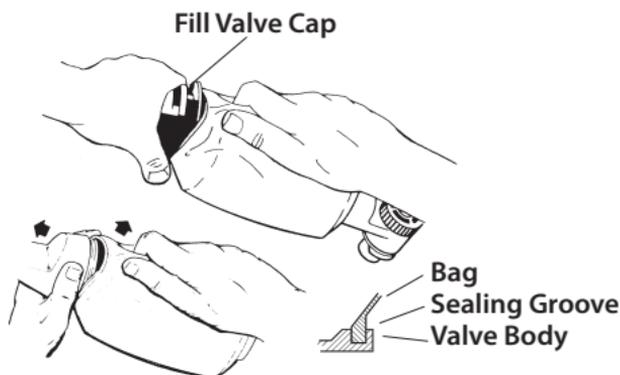


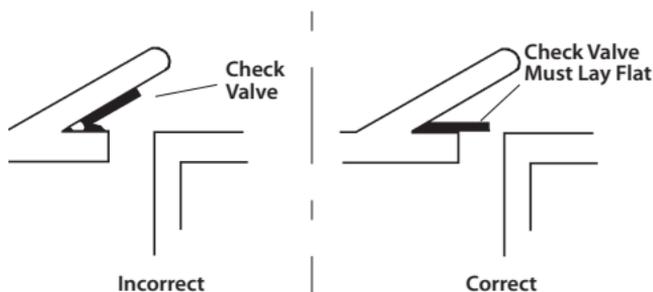
Figure 11



To Reassemble the Resuscitator:

1. Reinstall the check valve on the fill valve collar (be certain that only one check valve is installed). Gently pull the check valve away at intervals around the collar until the valve is flat (Figure 12).
2. Reassemble the non-rebreathing valve components (Figure 10):
 - Insert the diaphragm in the valve body. Be certain to install only one diaphragm.
 - Reinstall the O-ring on the valve cage and insert in the valve body.
 - Reinstall the cap on the valve body.
 - Reinstall the pressure port cap on the valve body.
3. Reassemble the non-rebreathing and fill valves on the bag. Be certain the sealing edge of the bag fits into the groove on the valve body (Figure 11).

Figure 12



CAUTION:

- The infant bag is designed to be assembled in only one way. The openings in each end of the bag are sized to fit the proper components only. The larger opening fits onto the non-rebreathing valve and the smaller opening fits onto the fill valve. Do not attempt to assemble these components in any other manner. The bag is labeled to assist in proper assembly.

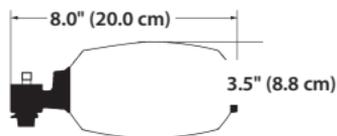
Specifications

Dimensions:

Infant	8.0" × 3.5" (20.0 cm × 8.8 cm)
Case	19" L × 11" D × 10" H

Weight (basic resuscitator, less mask):

Resuscitator	7.4 oz	210 g
Accumulator	2.0 oz	56 g
Case	5.2 lbs	2,360 g



Part Number: 153015-00

Operating Temperature Range:

0° to 122°F (-18° to 50°C)

Storage Temperature Range:

-40° to 140°F (-40° to 60°C)

Oxygen Concentration (average values %) Oxygen Supply Tube Only

Oxygen Flow				2 lpm	5 lpm	10 lpm	15 lpm
T.V.	bpm						
20 ml	60	C1/R400	I/E 1:1	97	99	99	99
150 ml	25	C10/R20	I/E 1:2	49	84	95	99

Accumulator Attached

Oxygen Flow				2lpm	5lpm	10lpm	15lpm
T.V.	bpm						
20 ml	60	C1/R400	I/E 1:1	—	—	—	>40
150 ml	25	C10/R20	I/E 1:2	—	—	—	>40

NOTE: Average values obtained during laboratory testing.

Connection Size:

Patient Connection: 15 mm/22 mm

Oxygen Connection: Accepts 3/16" to 1/4" ID tubing

Bag Volume:

520 ml

Infant Size Resuscitator Defined as:

Designed for use with infants with a body weight of <10 kg and requiring tidal volumes of 20 to 150 ml.

Average Dead Space*:

Non-rebreathing valve ≤ 7 ml

Inspiratory Resistance:

Does not exceed 5 cmH₂O at 5 lpm flow (air)

Expiratory Resistance:

Does not exceed 5 cmH₂O at 5 lpm flow (air)

Attainable Delivery Pressure:

270 cmH₂O

Ventilatory Frequency (bpm):

20 ml C1/R400 45

70 ml C10/R20 125

150 ml C10/R20 115

Maximum Stroke Volume (ml)**:		1-Hand	2-Hands
60 bpm C1/R400		65	120
25 bpm C10/R20		210	385

NOTE:

Test lung setting:

R = Resistance cmH20/liter per second

C = Compliance ml/cmH20

Cylinder Depletion Time at Flow of 10 lpm*:**

D size	volume 420 liters	42 minutes
E size	volume 690 liters	1 hour 9 minutes

*Values determined by water displacement.

**Hand size for testing conforms with ASTM F-920.

***Oxygen volume at 2015 psig and 70°F.

Components And Accessories

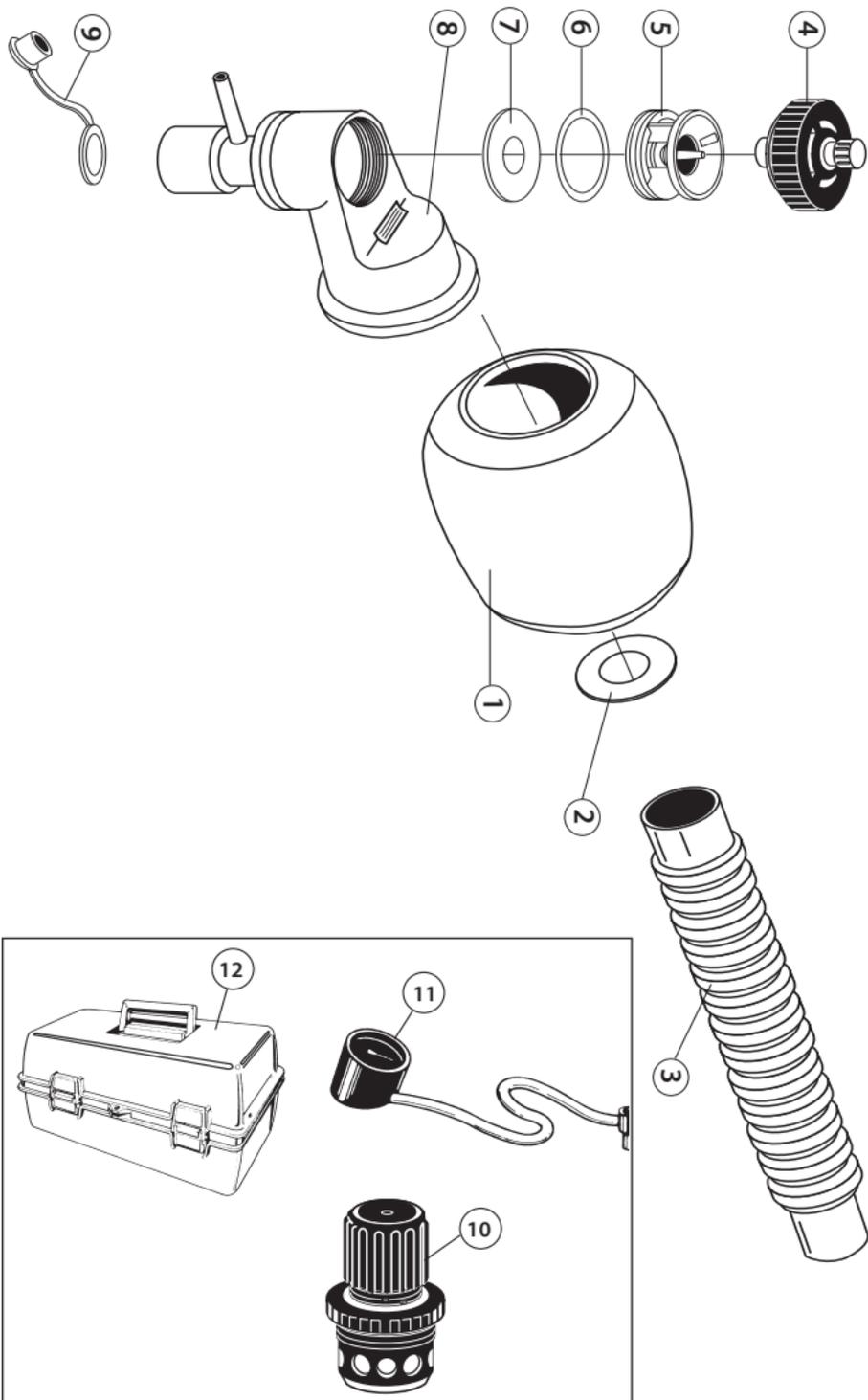
Item Part No.	Description	Material
1. 655035-00	Bag	Silicone (rubber)
2. 657003-PG	Check valve (pkg of 10)	Silicone (rubber)
3. 616416-00	Oxygen accumulator	Silicone (rubber)
4. 231136-00	Cap with relief valve	Nylon, stainless steel
5. 616078-00	Valve cage	Polysulfone (plastic), stainless steel
6. 622550-PG	O-ring (pkg of 10)	Silicone (rubber)
7. 631005-00	Diaphragm	Silicone (rubber)
8. 435021-PG	Relief valve label (pkg of 10)	Mylar (plastic)
9. 616408-PG	Pressure port cap (pkg of 10)	Silicone (rubber)

Item Part No.	Description	Material Accessories
10. 133179-00	PEEP accessory	
11. 130089-00	Airway pressure gauge	
12. 230473-00	Large case	
— 000612-00	Test lung (not shown)	
— 847567-00	Disassembly/reassembly wall chart	
— 847691-00	Operating manual instructions	

The PMR 2 resuscitator and accumulator do not require preventive factory service.

The Reusable Manual Resuscitator is warranted against defects in material and workmanship for one year in accordance with Nellcor Puritan Bennett™ warranty, form AA256.

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