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MANUAL RESUSCITATOR/RESUSCITADOR MANUAL ADUL.

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MANUAL RESUSCITATOR

User's Manual

Manual Resuscitator Instruction manual

CONTENTS

INTRODUCTIONS

The Manual Resuscitator is designed for use as an adjunct to artificial respiration and cardiopulmonary resuscitation. The Resuscitator can be used to ventilate the aphonic patient and to augment ventilation and / or oxygen delivery to the spontaneously breathing patient.

When connected to an oxygen source, the Manual Resuscitator can also deliver supplemental oxygen with the aid of an oxygen reservoir. The oxygen concentration delivered by the Manual Resuscitator delivered by the Manual Resuscitator depends on the oxygen supply flow rate, tidal volume, and ventilation frequency and operator technique.

The Infant and child models of the Manual Resuscitator are fitted with pressure relief valves which vent the delivered breath to the atmosphere if the pressure exceeds 40±5cm H_2O. The pressure relief valve can be overridden by the operator should a higher delivery pressure be required.

The Manual Resuscitator is intended for use by qualified medical and emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques. Users should read and understand the contents of this manual and demonstrate proficiency in the assembly, disassembly and use of this device prior to use.

CAUTIONS and WARNINGS

CAUTIONS

- **" Federal law restricts this device to sale by or on order of a physician." (CFR 21 801.109)**
- **Do not sterilize or decontaminate the single-use manual resuscitator.**
- For the reusable manual resuscitator, before use, clean and sterilize the entire Manual Resuscitator per your individual institution's validated procedure for cleaning and sterilizing such equipment. After the reusable manual resuscitator has been cleaned and sterilized well, test functionally the manual resuscitator as directed in this manual.
- The SILICONE / reusable Resuscitator device is autoclavable and can be reused **not more than 10 times, and every time the device will verify the post-sterilization functional and visual tests.** We will attach the label on the package.
- Replacement parts are intended for use on Manual Resuscitator only.
- Use only replacement parts in your Manual Resuscitator.
- Do not attempt to disassemble the pressure relief valve assembly. Disassembly will damage the component.

The SILICONE / reusable Resuscitator device is autoclavable and can be reusednot more than 10 times, and every time the device will verify the post-sterilization functional and visual tests.

WARNING

- Resuscitator must be used only by a person who has the received adequate training.
- Use of PEEP may have an adverse effect on cardiopulmonary status such as barotraumas and/or reduced cardiac output.
- Only qualified medical personnel trained in the use of PEEP should administer PEEP with this device.
- The use of a manometer with the manual resuscitator is required if no pressure-limiting system (POP-OFF valve) is incorporated in the device.
- The use of a manometer with the manual resuscitator is required to verify PEEP levels if integral to the resuscitator.
- Proficiency in the assembly, disassembly and use of this device should be demonstrated before use on a patient.
- Only qualified medical personnel trained in the use of PEEP should administer PEEP with this device.
- Use of PEEP may have an adverse effect on cardiopulmonary status such as barotraumas and/or reduced cardiac output.
- Overriding the pressure relief (POP-OFF) valve mechanism on resuscitator so equipped may lead to excessive ventilatory pressures that could have adverse effects on cardiopulmonary status such as barotraumas and/or reduced cardiac output.
- Improper ventilation with any resuscitator, with or without a pressure relief valve, may lead to excessive ventilatory pressures that could have adverse effects on cardiopulmonary status such as barotraumas and/or reduced cardiac output.
- Resuscitator should not be used in toxic, explosive or hazardous atmospheres without gas filtration.
- Remove the oxygen reservoir and reservoir valve if supplemental oxygen is not being administered. Failure to do so will affect refill rate and maximum ventilation frequency capabilities.
- Do not apply any oil lubricant, grease or other hydrocarbon-base substances on any part of the Manual Resuscitator. Supplemental oxygen, supplied with pressure will combine explosively with hydrocarbons.
- Always test the device according to the functional test procedure, shown in this manual, after reprocessing.
- During the emergency operation, always position the patient's head "according to current AHA technique".

Pre-use operation

1. To get the best effect, select a suitable resuscitator and a mask with which the patient can be fitted.
2. Inspect the components for any discoloration, erosion, or aging effect, and if find any one, please replace the components.
3. Resuscitator can be connected to a stationary or portable O_2 source by standard tubing. Readjust the O_2 flow rate to fill up the reservoir bag.
4. If the device is not connected to oxygen tubing, take off the reservoir bag.
5. Introduction of oxygen into the breathing circuit:

General instructions for operation

1. **Select** the appropriate size of Manual Resuscitator (infant, child or adult). Select the appropriate size of face mask if ventilation by mask is to be performed. Connect mask to outlet on non-rebreathing valve housing.
2. **If** supplemental oxygen is to be used, connect supply tubing (not supplied) between the regulated gas source and the oxygen reservoir inlet. Adjust gas flow so that the reservoir expands completely during the delivery of the breath and nearly collapses as the silicone bag refills.
   If supplemental oxygen is **not** to be used, **remove the reservoir and reservoir valve.** Failure to do so will affect the refill rate and maximum frequency capabilities.
3. **Should** the non-rebreathing valve become contaminated with vomit, blood or secretions during ventilation, disconnect the Resuscitator from the patient and clear the non-rebreathing valve as follows:
   Squeeze the silicone bag to deliver several sharp breaths through the non-rebreathing valve to expel the contamination. If the contamination does not clear, continue ventilation with another resuscitator or use mouth to mouth/mask techniques. Disassemble the non rebreathing valve and rinse in water. Reassemble and sterilize.
4. **Once** the procedure is complete, clean, sterilize and test the Resuscitator as described under **Cleaning & Sterilization** and **Testing the Resuscitator.**

PRINCIPLES OF OPERATION 1

The manual resuscitator consists of four major components (figure 1): non-rebreathing valve assembly (A), silicone bag (B), reservoir valve (C) and oxygen reservoir (D). parts C and D should be removed if supplemental oxygen is not to be supplied from an external gas source.

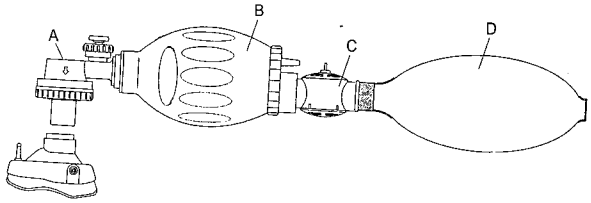


Figure 1. The Manual Resuscitator

Gas is delivered to the patient by squeezing the silicone bag (see figure 2). Positive pressure within the bag caused by its compression closes the intake valve (E) located at the base of the bag. This causes the 2 duckbill valve (F) to close off the expiration ports (G) of the non-rebreathing assembly. Further compression of the bag forces gas through the duckbill valve to the patient. If supplemental gas is used, oxygen is delivered to the reservoir (D) during compression of the silicone bag.

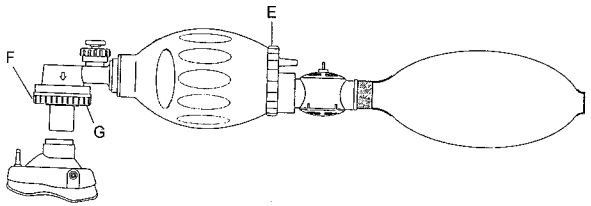


Figure 2. Inspiration

PRINCIPLES OF OPERATION 2

Exhibition begins when the patient exerts positive pressure (during passive exhalation) on the patient side of the duckbill valve (F) or when the operator releases pressure from the silicone bag (B). the valve lifts directing the patient's expiratory gases through the expiration ports (G) of the non-rebreathing valve (see figure 3)

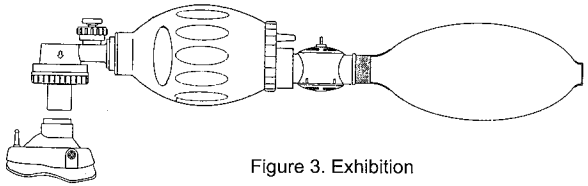


Figure 3. Exhibition

The silicone bag refills for the next breath during exhibition. Negative pressure within the bag (caused by the expansion of the compressed bag) opens the intake valve (E), allowing gas to enter the bag either from the atmosphere or from the oxygen reservoir (D).

The reservoir should be used whenever supplemental oxygen is delivered. (Supplemental oxygen may be administered without using the reservoir but the maximum available oxygen concentration will be reduced.) Excess oxygen vents to the atmosphere through the safety valve (H) on the reservoir (C) should the reservoir fill before the next delivered breath. If the volume of gas in the reservoir is inadequate to fill the silicone bag, room air may be drawn in through the reservoir valve safety inlet (I). The concentration of the oxygen-enriched gas entering from the reservoir will depend on factors such as oxygen flow rate, tidal volume, ventilation rate and operator technique.

PRINCIPLES OF OPERATION 3

The infant and Child models of the Manual Resuscitator are fitted with pressure release valves (see figure 4). These valves open when the pressure is in excess of 40 ± 5 cmH_2O.

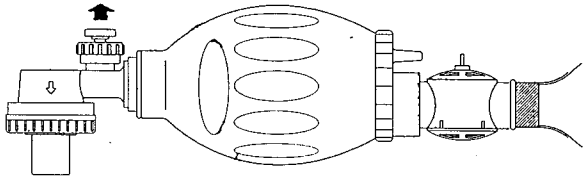


Figure 4. Pressure Relief Valve

Should higher inspiratory pressure be required, the pressure relief valve may be overridden by placing the thumb over the valve as shown in figure 5. It is also possible to lock the pressure relief valve in this position with #0100 (air valve bottom) Lock Type Non-rebreathing Valve. Just twist the valve a quarter turn and it will stay in the overridden position. (Arrow on the label forward to the NRV direction).

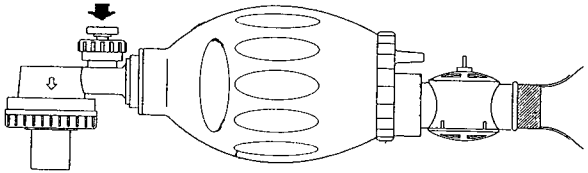
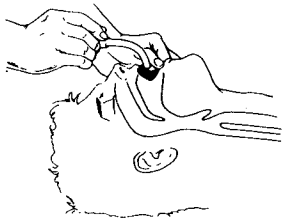
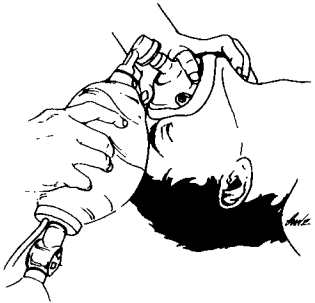


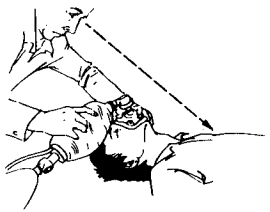
Figure 5. Overriding the Pressure Valve

Figure 6: Operating instructions for Manual Resuscitator



1. Place victim on back.
2. Clear mouth and throat of foreign material.
3. Insert oropharyngeal airway (if available), in accordance with the manufacturer's directions, to open the patient's mouth and prevent tongue from occluding the airway.
4. Position yourself behind the patient's head, extend the head back and pull the chin upwards and towards you to open the airway.





5. Hold mask firmly in place over the mouth and nose with thumb and index finger, using other fingers to grip the chin.
6. Inflate the lung by compressing resuscitation bag with the other hand. Develop rhythmic pattern allowing for adequate inspiratory/expiratory time.
7. Check to ensure that you are ventilating properly.
   - Observe rise and fall of the patient's chest.
   - Check the patient's lip and face color through the transparent part of the face mask.
   - Check that the patient valve is working properly through the transparent housing.
   - Check that the interior of the mask is being "fogged" during exhalation.

CLEANING AND STERILIZATION

The Manual Resuscitator should be cleaned and sterilized as follows:

- when first using the new Resuscitator
- between patients
- whenever the Resuscitator becomes contaminated
- every 24 hours of use with the same patient.

Carry out cleaning and sterilization as follows:

1. Disassemble the Resuscitator, and, if necessary, the face mask. See figure 6.
   Caution: Do not attempt to disassemble the pressure relief valve assembly as it can be cleaned without disassembly. Disassembly will damage the component.
2. Wash the components thoroughly in warm water containing a mild detergent. Ensure that the detergent is compatible with the component materials (**see Specifications).**
3. Rinse the components thoroughly in warm water to remove all traces of detergent.
4. Sterilize the components using one of the following methods:
   - all parts can be autoclaved (max: 132℃) **except** the oxygen reservoir.
   - all parts can be sterilized using ethylene oxide.
   - all parts can be sterilized using most common disinfecting solutions which are used for equipment coming into contact with the patient. Rinse thoroughly with water after sterilization.
5. The Silicone reusable Resuscitator device is autoclavable and can be reused **not more than 10 times, and every time the device will verify the post-sterilization functional and visual tests.**
6. Dry all components thoroughly after sterilization.
7. Inspect all components for wear. Replace as necessary.
8. Reassemble the Resuscitator as shown in figure 6.
9. Before use, test the Resuscitator as described in **Testing the Resuscitator.**
10. Put the Resuscitator in the protective bag supplied. A disposable bag for this purpose is provided with the Manual Resuscitator. Clearly mark the bag with the sterilization date.

TESTING THE RESUSCITATOR

The Manual Resuscitator should be tested as follows:

- when first using the new Resuscitator
- after cleaning and sterilizing.
- After any new parts have been fitted
- Monthly, if the Resuscitator is not frequently used.

Equipment required: Test lung, 0-100 cmH_2O manometer (for Infant and Child resuscitators only), flow meter, regulated gas supply, gas supply tubing.

ATTENTION:

PVC Manual Resuscitator is for single use only. Cannot be sterilized.

TESTING 1

Testing the silicone bag assembly

1. Remove the non-rebreathing valve and the oxygen reservoir and valve (if fitted).
2. Compress the silicone bag and occlude (block) the non-rebreathing valve outlet.
3. Release the bag. The bag should expand immediately and refill. If not, check that the intake valve at the base of the silicone bag is correctly assembled.
4. While keeping the non-rebreathing valve outlet blocked, compress the bag again. The bag should not compress easily. If this occurs, check that you are blocking the valve sufficiently, and that the intake valve at the base of the silicone bag is correctly assembled.

TESTING 2

Non-rebreathing valve assembly

1. Connect the non-rebreathing valve to the silicone bag. Connect the test lung to the outlet on the non-rebreathing valve.
2. Compress and hold the bag. The non-rebreathing (duckbill) valve inside the non-rebreathing valve should open and the test lung should fill. If not, check the connection between the Resuscitator and the test lung, and check that the non-rebreathing valve is correctly assembled.
3. Release the bag. The non-rebreathing (duckbill) valve should close and as the test lung deflates, gas should Flow through the expiratory ports in the non-rebreathing valve. If not, check that the non-rebreathing valve is correctly assembled.
4. Ventilate the test lung for a minimum of ten cycles to ensure that the Resuscitator is functioning correctly. Inspiration must occur when the silicone bag is compressed and exhalation when the bag is released. If no check that the non-rebreathing valve is correctly assembled.

To check the function of the pressure relief valve (Infant and Child Resuscitators)

Connect a 0-100 cmH_2O manometer to the patient outlet of the non-rebreathing valve. Compress the bag. When the pressure relief valve activates, the manometer should read 35-45 cmH_2O. If not, check that the non-rebreathing valve is correctly assembled and does not leak. If the pressure relief valve fails a further test, it must be replaced. Do not attempt to repair the pressure relief valve.

TESTING 3

Oxygen Reservoir/Reservoir Valve assemblies

1. Attach the reservoir to the reservoir valve assembly. Attach the silicone bag.
2. Inflate the reservoir and block the reservoir port.
3. Compress the reservoir bag. Gas should escape through the safety outlet valve on the reservoir valve. If not, check that the reservoir valve is correctly assembled.

4. Connect the reservoir and reservoir valve assembly to a Resuscitator.
5. Cycle the Resuscitator through several ventilations. The safety inlet valve on the reservoir valve should open during each refill to allow room air to enter the silicone bag. If not, check that the reservoir valve is correctly assembled.

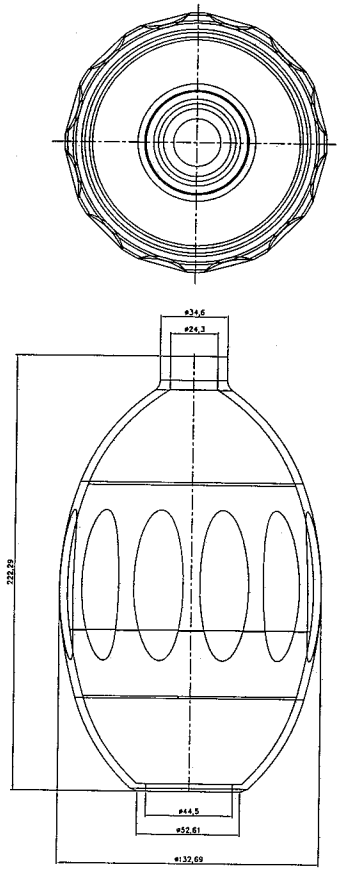
Note: If supplemental oxygen is **not** connected, the silicone bag will refill more slowly if the reservoir is still attached.

Overall Resuscitator function

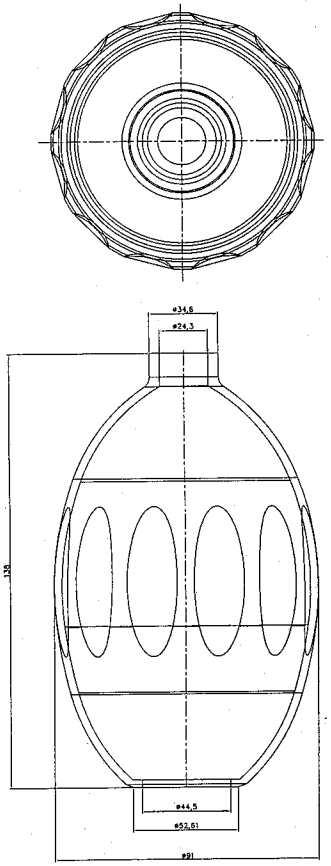
1. Fully assemble the Resuscitator (non-rebreathing valve, silicone bag, reservoir valve and oxygen reservoir). Connect the Resuscitator to a supplemental gas source and connect a test lung to the patient outlet on the non-rebreathing valve.
2. Set the supplemental gas flow to 15 LPM for the adult and child models; and to 10 LPM for the infant model.
3. Cycle the Resuscitator through several ventilations. The test lung should inflate during inspiration and deflate during exhalation. Check for leakage at all joints and connections. Ensure that the Resuscitator refills promptly and properly and that all valves are operating correctly. If not, repeat the tests above to find where the problem lies.

ILLUSTRATION :

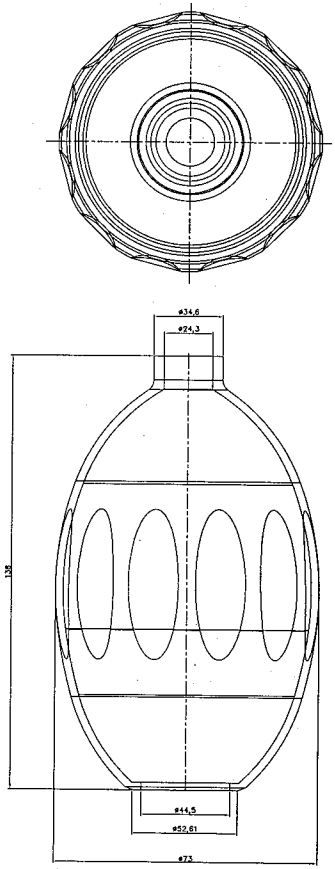
Large Size— PVC, ENT-1001
Silicone, ENT-1022



Middle Size— PVC, ENT-1003
Silicone, ENT-1024



Small Size— PVC, ENT-1005
Silicone, ENT-1014



Optional Accessories Operation:

(1) Mouth gag: put the gag on the tight teeth of the patient, and clockwise rotate the gag into the mouth to open the teeth of the patient.

(2) Air way: after the mouth of the patient is opened with the mouth gag, put the air way into the mouth until the throat, for directing the external air tubing into the throat. Fix the air way with the elastic band around the patient's head and face.

(3) Oxygen tubing: one end of the tubing connected to the oxygen cylinder or oxygen supply connector, another end connected to the oxygen connector of the intake valve part of the resuscitator, clearing out anything in the tubing and the connection.

(4) Nebulizer bottle **(not attached with this resuscitator)**: put the needed medicine in the bottle and input the compressed air of 9 LPM flow rate and 3.5 kg force through the down connector of the bottle, the liquid medicine being atomized, and the vaporized medicine will be pushed out to the up connector of the bottle and then the patient's mouth or nose.

SPECIFICATIONS 1

Storage temp.	-40℃/-10°F to 60℃/140°F
Operating temp.	-18℃/0°F to 50℃/122°F

(a)	Body mass range	Adult --- > 30 kgs / 67.5lbs Child --- 7 kgs / 15.75 lbs? 30 kgs / 67.5 lbs Infant — < 7 kgs / 15.75 lbs
(b)	Range of ventilatory frequency	Adult: 12 –15 times / minute Child: 14 – 20 times / minute Infant: 35 – 40 times / minute
(c)	Attainable delivery pressures without pressure limiting valve	> 1000 cmH_2O for adult > 370 cmH_2O for child > 270 cmH_2O for infant

Materials:

Silicone rubber	adult mask bladder, duckbill valve, flapper valve, mask grommet, Mask retainers, relief valve seal, silicone bag.
Polysulphone	adult mask shell, bag intake valve housing, non-rebreathing valve, housing, pressure relief valve housing, pressure relief valve , stem, reservoir bag connector, reservoir valve housing.
Polyvinyl chloride	oxygen reservoir bag.
Stainless steel	pressure relief valve spring.

Connections:

patient port	15mmI.D./22mm O.D.
silicone bag neck	24mm I.D.
reservoir valve	26mm I.D. (to silicone bag inlet) 25mm O.D.(to oxygen reservoir).
oxygen gas inlet	6mm O.D.

SPECIFICATIONS 2

Dead space: 6.8~7.0 ml for resuscitator

Inspiratory Resistance: 2.0 cmH_2O at 50 L/min

Expiratory Resistance: 2.0 cmH_2O at 50 L/min

Pressure Relief 40±10 cmH_2O (infant & child)
60±10 cmH_2O (adult)

Reservoir Volume 2500ml (adult and child model)
600 ml (infant model)

Bag volume
Stroke volume 1500/1350ml (adult model)
550/350ml (child model)
280/100ml (infant model)

Maximum BPM 45 breaths/min. (adult model)
105 breaths/min. (child model)
98 breaths/min. (infant model)

Oxygen Concentration
(connected to an oxygen source supplying)
adult and child model 90~95%
infant model 90%

Range of delivery pressure
Adult: Unrestricted of 60±10 cmH_2O
infant & child: 40±10 cmH_2O (can be overridden by operator)

Stroke volume range (typical values)
Adult Using one hand 800 ml
Using two hands 1350 ml
Child 350 ml
Infant 100 ml

PERFORMANCE CHARACTERISTICS

The performance characteristics for Manual Resuscitators will vary from user to user depending on a variety of factors: ambient temperature, patient lung compliance, ventilator frequency, size of operator's hands. The following data has been derived from Manual Resuscitators in accordance with ISO standards.

Frequency range

	Temperature -18℃/0℉ Cycle rate	22℃/72℉ Cycle rate	50℃/122℉ Cycle rate
Adult	38	45	45
Child A	92	105	105
Child B	72	78	76
Infant A	95	95	95
Infant B	60	60	60

These results were obtained under the following conditions:
Adult: V_T-600ml, Compliance -0.02 L/cmH_2O, Resistance -20 cmH_2O/(L/S)
Child A: V_T-70ml, Compliance -0.01 L/cmH_2O, Resistance - 20 cmH_2O/(L/S).
Child b: V_T-300ml, Compliance -0.02 L/cmH_2O, Resistance - 20 cmH_2O/(L/S)
Infant A: V_T-20ml, Compliance -0.001 L/cmH_2O, Resistance - 400 cmH_2O/(L/S)
Infant B: V_T-70ml, Compliance -0.01 L/cmH_2O, Resistance - 20 cmH_2O/(L/S)

PERFORMANCE CHARACTERISTICS

Adult

Values in parentheses are without an oxygen reservoir

O_2 flow in Tidal vol. (ml) x Ventilation rate

L/min	600x12	600x20	750x20	750x20	1000x12	1000x20
05	82(33)	58(33)	65(33)	99(30)	99(30)	85(30)
10	99(37)	80(37)	99(37)	99(37)	99(37)	99(37)
15	99(45)	99(45)	99(45)	99(45)	99(45)	85(45)

Conditions:

Compliance-0.02 L/cmH_2O, Resistance - 20 cmH_2O/(L/S). I:E ratio: 1:2.;

Child

Values in parentheses are without an oxygen reservoir

O_2 flow in Tidal vol. (ml) x Ventilation rate

L/min	70x20	70x30	200x20	200x30	300x20	300x30
02	99(65)	99(65)	58(37)	50(37)	45(34)	40(32)
05	99(86)	99(83)	99(44)	96(43)	84(37)	68(36)
10	99(93)	99(90)	99(46)	99(45)	99(45)	99(43)

Conditions:

V_T > 150 < 600 ml.

Compliance - 0.02 L/cmH_2O.

Resistance - 20 cmH_2O/(L/S)

I:E ratio: 1:2.

PERFORMANCE CHARACTERISTICS

Infant

Values in parentheses are without an oxygen reservoir

O_2 flow in Tidal vol. (ml) x Ventilation rate

L/min	20x30	20x60	40x30	40x60	70x30	70x60
02	99(72)	99(70)	99(70)	99(58)	99(55)	85(50)
05	99(77)	99(75)	99(74)	99(72)	99(65)	85(62)
10	99(94)	99(90)	99(90)	99(80)	99(79)	99(71)

Conditions:

V_T =20ml. Compliance-0.001 L/cmH_2O,

Resistance - 400 cmH_2O/(L/S).

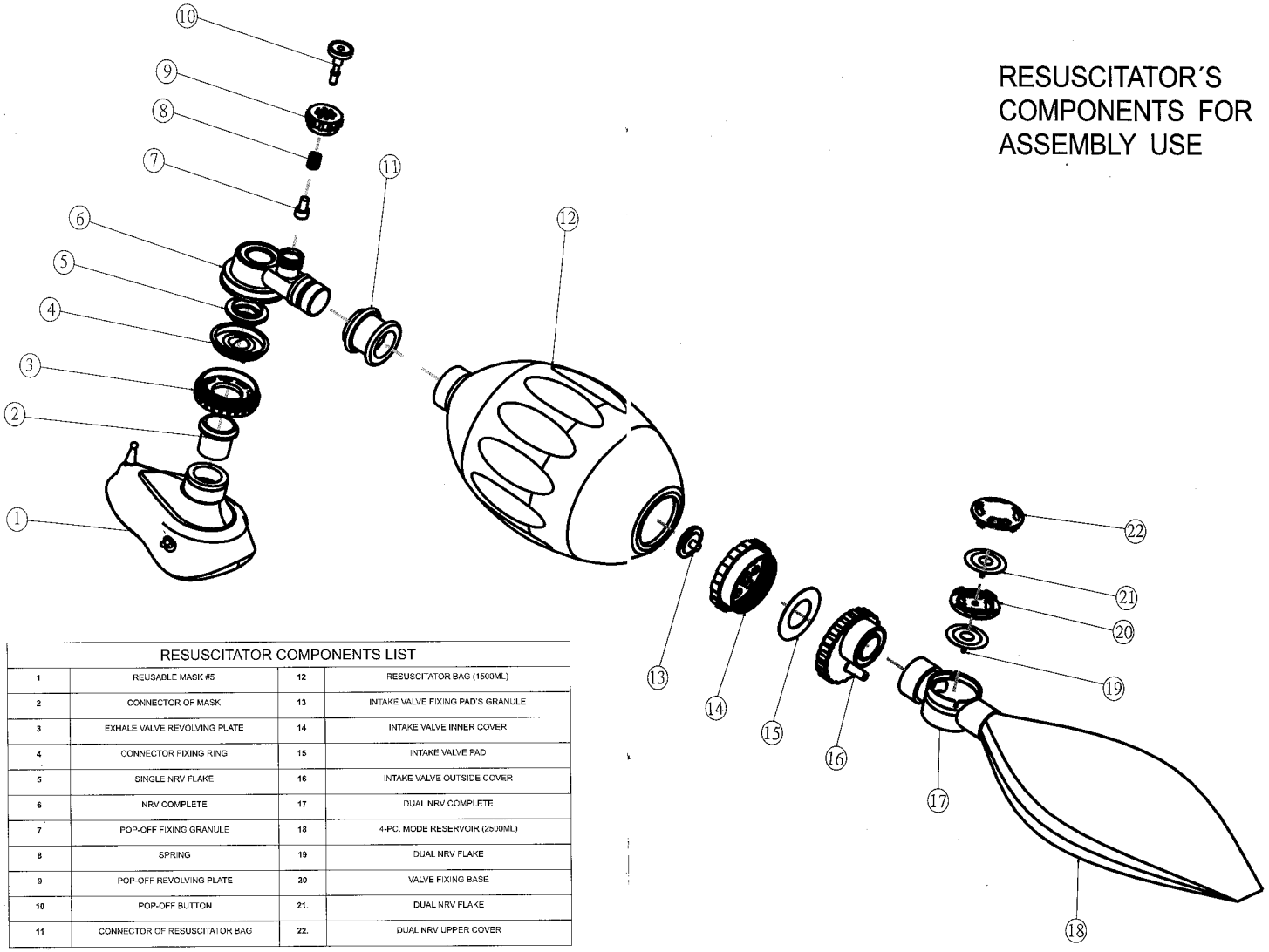
I:E ratio: 1:1.;

V_T =40 & 70 ml. Compliance - 0.01 L/cmH_2O.

Resistance - 20 cmH_2O/(L/S)

I:E ratio: 1:2.

RESUSCITATOR´S COMPONENTS FOR ASSEMBLY USE



RESUSCITATOR COMPONENTS LIST			
1	REUSABLE MASK #5	12	RESUSCITATOR BAG (1500ML)
2	CONNECTOR OF MASK	13	INTAKE VALVE FIXING PAD'S GRANULE
3	EXHALE VALVE REVOLVING PLATE	14	INTAKE VALVE INNER COVER
4	CONNECTOR FIXING RING	15	INTAKE VALVE PAD
5	SINGLE NRV FLAKE	16	INTAKE VALVE OUTSIDE COVER
6	NRV COMPLETE	17	DUAL NRV COMPLETE
7	POP-OFF FIXING GRANULE	18	4-PC. MODE RESERVOIR (2500ML)
8	SPRING	19	DUAL NRV FLAKE
9	POP-OFF REVOLVING PLATE	20	VALVE FIXING BASE
10	POP-OFF BUTTON	21.	DUAL NRV FLAKE
11	CONNECTOR OF RESUSCITATOR BAG	22.	DUAL NRV UPPER COVER