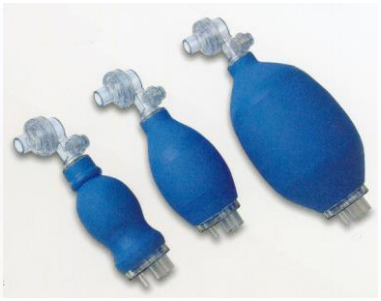
RESUSCITATOR BAGS AND ACCESSORIES

ALL-IN-ONE
OB VENTI-BAG

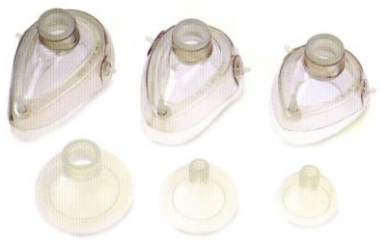
USER MANUAL

Silicone resuscitator bags

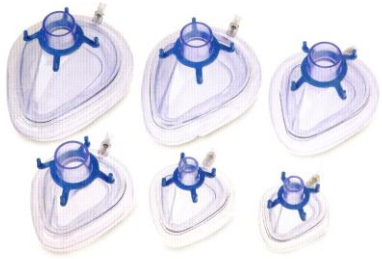
PVC resuscitator bags



Rubber resuscitator bags



Silicone masks



PVC masks

Rubber masks

CE 0123

PRODUCED BY:

BOSCAROL®

Emergency Medical Systems

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www.boscarol.it

INDEX

1. WARNINGS AND PRECAUTIONS

PLEASE READ CAREFULLY!

- The use of this medical device is permitted only to appropriately authorized and trained persons.
- Do not sterilize the device and the disposable parts marked with the symbol shown at right →.
- Do not use the resuscitator bag in rooms where the air is toxic or contaminated, in presence of explosives or where the air may be contaminated with anesthetic agents.
- Before using the reusable silicone resuscitator bag, clean and/or sterilize it. Proceed with a full functional testing, after sterilization/disinfection, before using the device on patients.
- Only use original spare parts, provided by the manufacturer (Oscar Boscarol srl).
- Do not use any type of grease, oil or other lubricant on the device (including hydrocarbon-based substances). These substances, in combination with oxygen, can trigger combustion and/or spontaneous outbursts.
- Do not remove the safety valve on the resuscitator bag. Its dismantling may cause immediate damage.
- Before using the device on patients, the user must be able to disassemble/reassemble all its parts and must be aware of all the maintenance and reuse operations.
- Improper ventilations performed with devices with and without the safety valve may create harmful effects to the patient's cardio-respiratory system.
- During the emergency ventilation always place patient's head in order to ensure the passage of air or oxygen into the airways.

WARNING ON REUSE OF DISPOSABLE PARTS

- Reuse of disposable parts/components may compromise the device function and be direct or indirect source of operator and patient injures. The disposable parts/components are manufactured with substances and processes which do not guarantee their operation in a safe way and in compliance with the imposed requirements if reused
- The sterilization and/or cleaning of disposable parts (antibacterial filters, suction tubes, Yankauer suction catheters, etc.) can cause structural damage leading to the risks of lost mechanical integrity. All parts/components treated with autoclavable sterilization processes can be 100% destructive (result of melting, burning and chemical alteration) and damage the use of the autoclave itself

2. INTRODUCTION AND APPLICATIONS

The manual resuscitator bag has been designed as an instrument for assisted pulmonary ventilation.
The ergonomic construction of its components, the technical materials used, and the assembly system are the result of experience and "know how" in the medical field.
The resuscitator bag is an independently medical device and can be used without external accessories.
It can be used connected to ventilation masks or directly to endotracheal cannulas. You can connect the resuscitator bag to a source of therapeutic oxygen (with optional tubing not included) and provide it with a reservoir to ensure optimal dosing.
All resuscitator bags are available with and without overpressure valve. Adult resuscitator bags have an overpressure valve settled at 60cmH2O (588,36 Pa), while pediatric and neonatal one at 40cmH2O (392,24 kPa). If necessary, the valve can be deactivated with a simple twist or pressure.
The resuscitator bag is designed and manufactured for professional use and it is intended for trained and competent users. Users should read carefully this user manual before using the device, to learn the correct use, cleaning, disassembly and reassembly.

3. PRINCIPLES OF OPERATION

The Boscarol resuscitator bag is a manual and portable device for the respiratory emergencies. The device ensures the administration of air or oxygen through the manual compression of the bag itself. It is recommended to use the device complete with Boscarol mask, choosing the proper size, to ensure a perfect grip the nose-mouth. The masks are available separately.
The Oscar Boscarol provides different device dimensions, depending on the patient's body size: this allows to obtain the maximum benefits for the patient in critical respiratory conditions. Ventilation masks are available in sizes ranging from 0 (infant) to 5 (adult).
Other optional accessories are available for the completion of the device (see list of the manufacturer).
Depending on the production material, the Boscarol resuscitator bag could be **REUSABLE** or **DISPOSABLE**. Reusable resuscitator bags are made with specific materials (silicone and polycarbonate) to ensure the properties of sterilization without damages. The other resuscitator bags, made with PVC or rubber synthetic materials, cannot be sterilized and should be considered disposable.

ATTENTION! Disposable devices are identifiable by the labeling on their packaging. Once opened the packaging, the device can only be used once. After use, the device must be disposed!

The operating principle of the device based on specific non-return valves installed on the device. Hitting the resuscitator bag with the hands, the pressure conveys the air contained in the bag to the exit connected to the patient's mouth. Thanks to a non-return valve, the air in the resuscitator bag cannot flow to the bottom of the device. The amount of air or oxygen flowing towards the patient's mouth depends on the force exerted on the resuscitator bag by the rescuer and on the maximum volume permitted by the device (or by the reservoir, in case of use of oxygen).
The patient's exhaled air cannot flow back to the resuscitator bag due to the non-return valve and thanks to a special mechanism it goes outside (to the ambient).

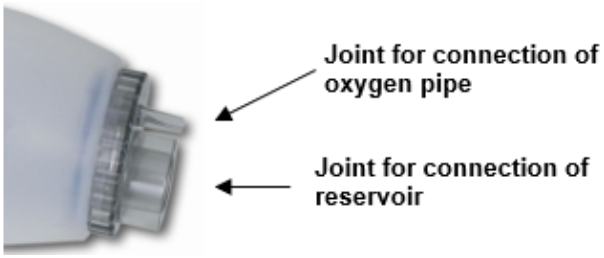
ATTENTION! If oxygen is not administered, disconnect the reservoir and the connecting pipe for the connection to the oxygen source! Close the oxygen cylinder if not used!

Suggested ventilation bags according to the weight of the patient

Adult ventilation bag	For adult/child over 30 Kgs (about 66 lbs)
Child ventilation bag	For child up to 30 Kgs (about 66 lbs)
Infant bag	For infant till 10 Kgs (about 22 lbs)

3.1 Before using on patients

Before starting to use the device on the patient it is necessary to ensure its full and proper functionality (both of resuscitator bag and of all the accessories included). Inspect the complete device to identify problems of discoloration, surface erosion, safety valve malfunctions, breaks or tears. If functional problems are detected, immediately put the device out of service. Ask the manufacturer for the original spare parts.



The resuscitator bag can be connected to a portable or stationary oxygen-source through a standard tube. Adjust oxygen to obtain a correct filling of the reservoir. Pipe connection to oxygen shall be connected to the junction near the reservoir connection (see image on the side).

The ALL-IN-ONE resuscitator bag embodies the valve that allows the regular filling of the resuscitator bag even if the oxygen source pressure doesn't allow it. In this case, oxygen is mixed with ambient air.

Example of a complete device, consisting of ventilation mask, resuscitator bag, reservoir and oxygen tube. The reservoir must be connected on the bottom of the device (see above picture)

3.2 Use on patients

During ventilation ensure the following conditions of the patient:

1. Spontaneous or controlled respiratory rhythm
2. Correct operation of the "lips-valve" situated on the mask connector
3. If the device is connected to oxygen, check the correct filling of the reservoir
4. If during the ventilation the color of patient's face became dark/dark purple (suspected respiratory deficiency) it is necessary to check the results of previous operations and immediately inform a doctor

ATTENTION! After each use reusable devices must be decontaminated and/or sterilized, while disposable ones should be removed!

3.3 Optional accessories

Auxiliary accessories for the device are available to facilitate the operations of emergency ventilation (e.g. helicoidal mouth/teeth opener, Guedel airway, oxygen tubes ready to use). Ask Oscar Boscarol srl for them.

4. GENERAL INSTRUCTION FOR USE

Before starting with the ventilation, make sure that the patient is in stable and with face upward.

Verify that patient's mouth and upper airways are free of obstructions (liquid and solid substances).

Insert an airway into the mouth of the unconscious patient to ensure the opening of the airway and prevent obstruction of the trachea due to the collapse of the tongue.

A mask should be applied to the Boscarol resuscitator so to completely cover both nose and mouth. Make sure that the edge of the mask adheres perfectly to the face. If available, use suitable masks size for patient's face.

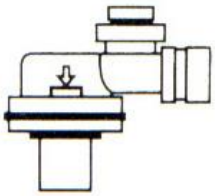
To facilitate ventilation operations the bag can rotate the most comfortable position for the rescuer. Keep the mask well supported with one hand on patient's mouth and nose, and with the other begin the ventilation cyclically, pressing rhythmically the body of the resuscitator bag.

The number of ventilations per minute depends on many factors, such as the patient's disease or the adopted therapy. We can say that normally respiratory cycle is:

ADULT	12÷15 breathing acts	CHILD	14÷20 breathing acts	NEWBORN	35÷40 breathing acts

During respiration or ventilation, rescuer must continuously make sure of patient's health: observe the thorax which expands and contracts for breathing, the colour of lips and face, the heartbeat.

If the administration of oxygen is necessary, the use of the reservoir should be a good choice. Normally the reservoir works properly when filled up completely during patient exhalation and empties during his inspiration (obviously the quantity administered to the patient depends on the rescuer).
If the gas pressure is not enough to completely fill the bag, a special valve can compensate the aspiring air from the environment, ensuring proper ventilation. In this case oxygen concentration decreases.
The concentration of oxygen administered to the patient therefore depends on many factors (oxygen flow towards the resuscitator bag, number of breathing acts, operator's technique, etc.).

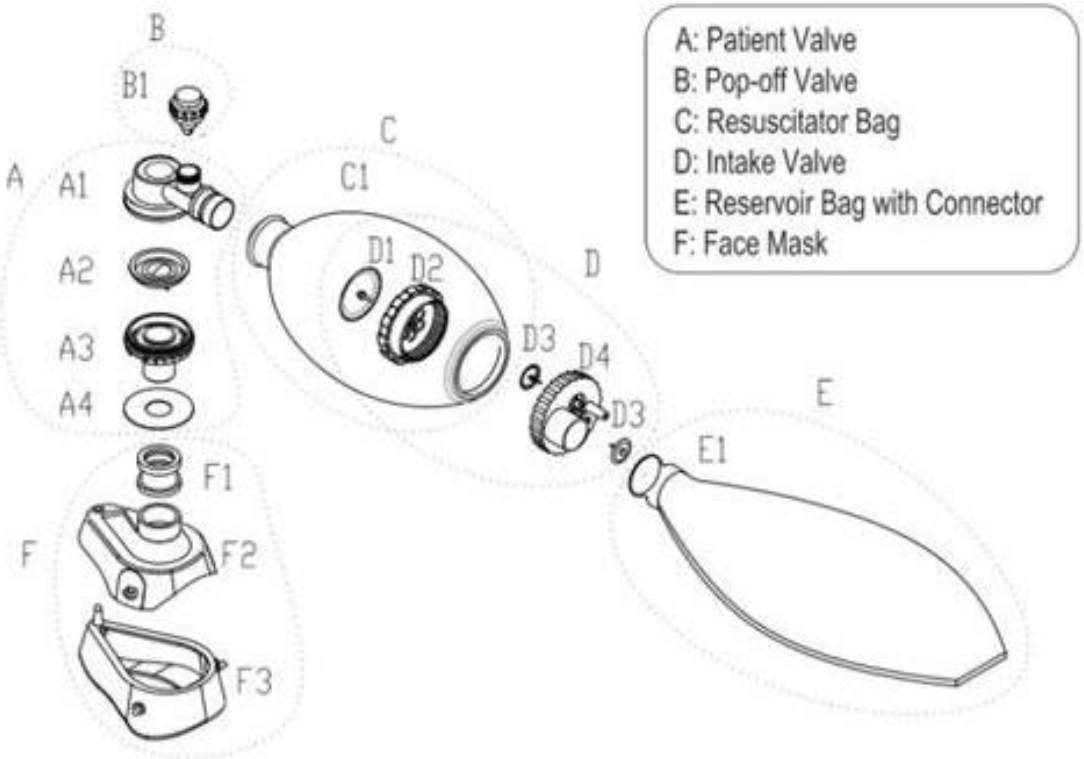


If blood, vomit or other substances from the patient's mouth partially or completely block the "lips-valve" on the resuscitator bag (close to the connector to the mask), remove the resuscitator bag complete with mask from patient's face and remove substances that block its operation, proceeding in this way: in a safe location, away from the patient's face, repeatedly act one-handed (or both) on the body of the bag, exerting great pressure and ensure that such substances might be expelled from the device.
It is usually possible to restart ventilation regularly, but if this is not possible, use another resuscitator/ventilator or proceed with the mouth-to-mouth breathing using a specific mask.
After each use carefully clean all parts as described in Chapter 6 of this manual. Before reuse the device, always be sure of its full functionality.

5. CONFIGURATION OF THE DEVICE AND SPARE PARTS

5.1 Device structure

Boscarol resuscitation bags are equipped with different safety valves that allow to release excess air or oxygen (or both mixed). The valve "A" is called "patient valve" while the valve "B" is called "pop-off valve". The pop-off valve opens with pressures equal to or greater than 40 or 60cm H_2O (with a tolerance of ± 5%). To select the right value, raise the valve and rotating it. In the next figure the scheme of the ventilation bag and its safety valves.



Ref No.	Description	Material
	A. Patient Valve	
A1	Upper patient valve	Polycarbonate
A2	One way valve	Silicone
A3	Lower Patient valve with mask connector	Polycarbonate
A4	Patient valve O ring	Silicone
	B. Pop Off Valve	
B1	* Pop Off Valve	Polycarbonate
	C. Resuscitator Bag	
C1	Resuscitator Bag with connector	Silicone + Polycarbonate
	D. Intake Valve	
D1	Big silicone valve	Silicone
D2	Inner all in one valve	Polycarbonate
D3	Small silicone valve	Silicone
D4	Outer all in one valve	Polycarbonate
	E. Reservoir bag with connector	
E1	Reservoir bag with connector	PVC+ Polycarbonate
	F. Face Mask	
F1	* Face Mask Connector	Silicone
F2	* Face Mask Dome	Polycarbonate
F3	* Face Mask seal	Silicone

The figure shows the composition of the device and its accessories. The masks can be disposable or reusable while the reservoir is always disposable. The outlet plastic fitting (made by polycarbonate) and complete with the safety valve (called "duck's beak"), also includes the pop-off safety valve (overpressure). Always be very careful, after disassembly the device, to reassemble it correctly. Carefully follow the figure on the previous page if in doubt.

5.2 Device safety

The device is designed to ensure maximum reliability both in terms of safety and performance: a "non-return" safety valve (duck's beak), placed in the outlet fitting to the patient, prevents the backflow of fluid substances / liquid and air exhaled by the patient inside the ventilation bag. The other valve, called pop-off, is calibrated to opens if the pressure inside the bag reaches too high values. The pop-off valve is calibrated by the manufacturer and may have intervention pressures at 40 or 60 cmH_2O (approximately 392 or 588 Pa*). The non-return valve instead placed in the air or oxygen inlet part (special group D of the previous figure) serves to make the compressed air in the bag be directed towards the outlet (i.e. towards the mouth of the patient). D1 and D3, contained in the inlet valve block, allow the complete filling of the reservoir.

*** Pa = Pascal (1 Pa = 0,01 mbar)**

5.3 Spare parts

Spare parts for this device are available only for the reusable resuscitator bag (silicone). For codes and list always refer to Oscar Boscarol srl company.

6. CLEANING AND STERILIZATION

ATTENTION! THESE OPERATIONS ARE EXCLUSIVELY EXECUTABLE ON SILICONE REUSABLE DEVICES. CLEANING AND STERILIZATION OF DISPOSABLE DEVICES IS STRICTLY FORBIDDEN!

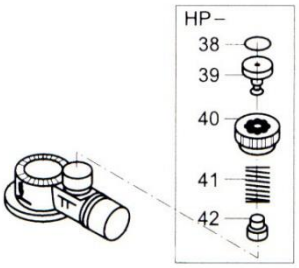
6.1 After use

After each use on patients, or every 24 hours, provide specific cleansing and disinfection operations as described below. If the devices are disposable (indicated by the symbol applied on packaging – see here on the side) they must be disposed according to local and national regulations.

6.2 Cleaning

Before beginning the following steps, ***make sure that you are working with silicone reusable devices***. Disassemble the device following the scheme at the previous page. Pay attention to the part named HP (see picture): it is a balanced valve, which cannot be disassembled. This valve, mounted on polycarbonate junction to the mask-connector, can be safely cleaned, disinfected or sterilized without dismantling.

Proceed as follows, in order to clean and sterilize the device correctly:



1. Protect your hands with individual PPE (gloves, etc.)
2. After having dismantled all the components of the device wash them in warm water with a non-aggressive cleaning
3. After the wash rinse all parts with lukewarm water
4. If you want to proceed with sterilization, follow the directions of next paragraph. Otherwise, dry all parts with a soft cloth that does not loose fibres
5. After drying, reassemble the device according to the previous page
6. Before using the device perform a functional test, as described in paragraph 6.4

6.3 Sterilization of the device

The device is not sold sterile. The user can sterilize it according to different types of process documented below, according to hospital practice. It is important to sterilize the device only when it is completely disassembled.

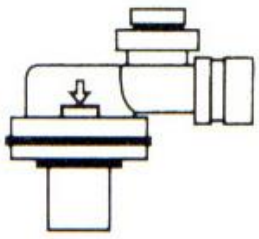
The device can be sterilized as follows:

1. Steam autoclave sterilization at a maximum temperature of 136° C (277° F) at a pressure of 2 bar (200 kPa), for 30 minutes maximum. **The reservoir cannot be sterilized**
2. "ETO" sterilization (carbon monoxide)
3. Through specific substances used in the hospital and ensuring the effectiveness of the process. The process must be in accordance with current hospital provisions and evidence shall be provided to validate the process
4. After each process of sterilization (regardless of the type) it is necessary to wash all components under clean, lukewarm running water
5. Dry all components with a soft cloth and ensure their technical and functional integrity. If some components are faulty or have structural abnormalities replaced them
6. Reassemble the device according to the design of the previous page
7. Perform a complete functional test as described in the next paragraph
8. Keep the tested device in the nylon bag provided by purchasing
9. Note on the packaging with a marker last performed sterilization

ATTENTION!
It is possible to sterilize the device until the first failure of functionality test or visual inspections. The manufacturer recommends performing accurate inspections on device surface after each operation of disinfection and/or sterilization!

6.4 Functional testing of the device

The device must be tested after the purchase, after each cleaning and/or sterilization process, after assembly operations and every time there are doubts about its functioning. If the device is not frequently used, it should be tested at least once a month.
Please follow the testing procedure on the next page.



1. To verify the correct operation of the intake valve, remove the reservoir. Remove the mask-connector and compress the resuscitator bag with one hand, releasing the contained air. Close the higher output (the one from which the air was able to exit) with the palm of the other hand and release the bag.
   The resuscitator bag must fill itself immediately thanks to the air valve placed at the bottom of the bag itself. If this does not happen, check the valve on the bottom of the resuscitator bag and if necessary replace it with a new one. Also check the correct assembly.
2. Assemble the mask-connector on the resuscitator bag (see figure above) and, if present, close the POP-OFF valve (turn it 180° to "lock" indication). Close the outlet to the mask with the palm of the hand. Compress the resuscitator bag with the other hand: it shouldn't be easy. Otherwise verify the correct assembly of the valve at resuscitator bag's bottom. If the POP-OFF valve does have any leakages, it means that it isn't in "lock" position. Raise the valve plunger with the hand and turn it 180°.

3. To verify the correct operation of the safety valve in the mask-connector, first ensure the correct assembly of it and then, without blocking the exit, compress the resuscitator bag. The air must freely exit from the "lip-gasket" mounted in the mask-connector. When you release the bag, the seal must be closed. Compress and release repeatedly the resuscitator bag to ensure its correct operating (being the connecting tube section less than the inlet valve, the fill will be slower).
4. Connect the reservoir to the resuscitator bag. Compress and release the bag. Rapid re-expansion confirms the efficiency of the integrated valve and reservoir. Compress and release repeatedly the resuscitator bag, verifying the correct funcioning of valve and reservoir. A rapid re-expansion of the resuscitator bag after releasing means that the valve operates properly.

ATTENTION! Immediately replace any defective or faulty component

7. MAINTENANCE

No parts/components of the device require periodic maintenance. Only standard functional testing is required, as described in this manual. In case of defects, malfunctions or tests failure, replace the device with a new one. In case of doubts please always refer to the manufacturer Oscar Boscarol srl, Enzo Ferrari street 29, 39100 Bolzano.

8. CLASSIFICATION, TECHNICAL DATA AND FEATURES

8.1 Device classification referred to Italian D. lg. 46/97 (MDD 93/42/CEE and subsequent amendments)

Manual resuscitation device that allows forced administration of air, oxygen or mixture of air and oxygen to patients with respiratory deficiencies. The device can be reusable or disposable, depending on the manufacturing materials. It allows the connection of masks with standard joints.

Device classification according to D. lg. 46/97:	IIa
Device compliant with the ISO reference standard:	ISO 10561-4:2009 (Lung)
Power source:	Ambient air or therapeutic oxygen (O_2) at low pressure and controlled rate.
Connection to O2 source:	Directly to the device, through standard tube.
CE mark on the device:	CE0123 (TÜV ITALIA srl) CE 0123

8.2 Technical characteristics of the device

Pressure attainable without pressure limiting valve:
> 100kPa (1bar) for ADULT
> 360kPa (0,36bar) for CHILD
> 260kPa (0,26bar) for NEWBORN

Ventilation bag type	Adult (> 30 kg)	Child (7÷30 Kg)	Infant (< 7 Kg)
Bag Volume (ml)	1800	550	320
Stroke Volume (ml)	1080	320	140
Reservoir Bag (ml)	2700	2700	900
Expiratory/Inspiratory resistance	2.0 cmH_2O/4.0 cmH_2O		
Dead Space	Less than 7.0 ml		
Pressure relief (optional)	40 or 60 cmH_2O	40 cmH_2O	
Operating temperature	-18÷50 °C (test according to the EN ISO 10651-4:2009		
Storage Temperature	-20÷60 °C (test according to the EN ISO 10651-4:2009		

Higher respiratory pressure can be obtained by overriding the pressure limiting device, use only if medical assessment indicates the need.

8.3 Connections

Description	Dimensions
Patient port	15 mm / 22 mm OD
Bag neck	25 mm ID
Reservoir valve	26 mm ID (to bag inlet) / 25 mm OD (to oxygen reservoir)
Oxygen gas inlet	6 mm OD

ID = internal diameter OD= outside diameter

Oxygen concentration delivered under different conditions (specified in the tables below). Values in parenthesis are referred to the device without reservoir.

ADULT resuscitator bag

ADULT	Ventilation bag volume 1700ml – Reservoir volume 2700ml					
Flow O2	(TIDAL) Delivered volume x ventilation rate					
L/min	600x12	600x20	750x12	750x20	1000x12	1000x20
5	83(32)	58(34)	65(34)	50(30)	55(31)	45(31)
10	99(37)	80(38)	99(37)	99(36)	88(36)	62(36)

15	97(46)	97(45)	97(46)	97(44)	97(44)	90(46)

CHILD resuscitator bag

CHILD	Ventilation bag volume 500ml – Reservoir volume 2700ml		
Flow O2	(TIDAL) Delivered volume x ventilation rate		
L/min	70x30	200x30	300X30
5	96(66)	59(38)	45(33)
10	97(82)	97(48)	69(38)
15	97(89)	97(48)	97(44)

NEWBORN resuscitator bag

NEWBORN	Ventilation bag volume 350ml – Reservoir volume 900ml			
Flow O2	(TIDAL) Delivered volume x ventilation rate			
L/min	20x30	20x60	40x60	70x60
5	97(75)	97(72)	92(59)	85(52)
10	97(75)	97(78)	97(78)	86(61)
15	97(95)	97(92)	97(82)	97(73)

Oxygen tube connector: 6mm external diameter

Average volume for compression:
Adult: 900ml
Child: 250ml
Newborn: 130ml

Maximum loss: < di 0,7ml for all versions
Resuscitator bag nominal volume: 305ml (newborn), 478ml (child) , 1778ml (adult)

Breathing resistance:

Adult inspiration/exhalation 2,2cmH2O (215Pa) / 3,3cmH2O (323Pa) for 50LPM
Child inspiration/exhalation 2,2cmH2O (215Pa) / 3,3cmH2O (323Pa) for 50LPM
Newborn inspiration/exhalation 2,2cmH2O (215Pa) / 3,3cmH2O (323Pa) for 50LPM
Exhalation final pressure (normal use conditions) 3,2cmH2O (323Pa)
Pressure setting POP-OFF valve 40cmH2O (3920Pa) – manual block

Unloading pressure of patient valve:
NEWBORN 87cmH2O (8530Pa)
CHILD 101cmH2O (9900Pa)
ADULT 138cmH2O (13500Pa)

Dimensions and weights (without accessories):

Adult version: 325x130x130 mm – 314 gr. (±5 %)
Child version: 255x91x91 mm – 194 gr. (±5 %)
Newborn version: 256x85x74 mm – 158 gr. (±5 %)

LIFETIME OF THE DEVICE: maximum 5 years if the device is tested and verified monthly!

BOSCAROL®

Emergency Medical Systems

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