BOSCAROL MANUAL RESUSCITATORS

RESUSCITATOR BAGS AND ACCESSORIES

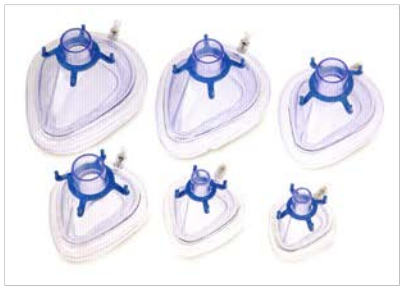
OPERATING INSTRUCTIONS

Silicone resuscitator bags

PVC resuscitator bags

Rubber resuscitator bags

Silicone masks



PVC masks

CE 0123

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Information on manufacturer and medical device:

- Oscar Boscarol applies a quality management system compliant with international standards ISO 13485 and ISO 9001.
- The medical devices of category "Manual resuscitation" (in all their configurations) are compliant with MDD 93/42/EEC (as subsequently amended) and bear the CE marking (CE 0123 notified body TÜV SÜD PRODUCT SERVICE GmbH).
- The medical devices meet the essential requirements described in annex I of MDD 93/42/EEC.

Information on these operating instructions:

- This document contains important information for safe, effective and compliant use of the medical device.
- Use this information to train users and confirm their training.
- This manual may not be modified in any way (not even partially). Only the device manufacturer can make changes when necessary.
- These instructions must always accompany the device. We recommend using the electronic version and making it available on operator PDAs, tablets and cell phones.

These operating instructions apply to the following devices:

- Resuscitator bags and accessories

REF CODE:

PAL32000	PAL32004	PAL32010	PAL32014	PAL32050	PAL32054	PAL32058	PAL32062	PAL32066
PAL32070	PAL32100	PAL32104	PAL32110	PAL32114	PAL32120	PAL32124	PAL32150	PAL32154
PAL32158	PAL32162	PAL32166	PAL32170	PAL32200	PAL32210	PAL32220	PAL32350	PAL32356
PAL32370	PAL32375	PAL34350	PAL34356	PAL34371				

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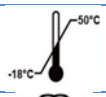
0 MEANING OF SYMBOLS AND PICTOGRAMS

0.1 Symbols used in these operating instructions to call the reader's attention

	Danger: important safety-related information covering correct use of the resuscitator bag to prevent operator or patient injury and/or damage to unit itself
	Warnings: information requiring special attention
	Notes or information on preventing damage to the device or injury to others. Implement correct prevention measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	Maintenance service required (contact the manufacturer and/or its authorized service centres)

0.2 Symbols used on the device and accessories

	Use the resuscitator bag only within the specified temperature range. Using the resuscitator bag outside these limits could compromise its functional performance and damage it.
	Read these operating instructions carefully and thoroughly
	Accessories and/or consumables displaying this symbol are disposable. They cannot be reused and, after use, must be discarded and replaced with new ones.
	Indicates that the user must consult these operating instructions for information, e.g. warnings and precautions that may not be displayed on the medical device in question
CE 0123	CE marking in accordance with MDD 93/42/EEC for medical devices rated higher than class I
	Manufacturer
	Date of manufacture
	Expiry date
REF	Order number (device code)
LOT	Production batch
	These operating instructions are available in other languages on the indicated website. Please read them.
MD	Indicates that the resuscitator bag is a medical device

1 INTENDED USE

Device name	Resuscitator bag and accessories
Primary use	Portable, manually operated device used in life emergency situations to provide lung ventilation (by means of pressing the compressible part of the device) to patients with respiratory deficiencies.
Medical Purpose	Manual ventilation of patients with apnea (suspension of pulmonary respiration) or insufficient respiration
Site of application to human body	Resuscitation masks are intended to be used on the patient's face, covering the nose and mouth
Patient type	Adults, children, and infants of both sexes. The size and shape of the resuscitator bags and masks are different for use in the adult, pediatric and neonatal setting to meet the different needs of compression frequency and volume of oxygen required.
Length of application on a given patient	"Short-term" use (maximum 60 continuous minutes on the same patient)

Information on usage	• The resuscitation bags are available in three different materials: rubber, PVC and silicone. Resuscitation bags in rubber and PVC are available in neonatal, child and adult versions. Silicone resuscitation bags are available in child and adult versions. • The ventilation masks are available in two different materials: silicone and PVC. each type is available in six sizes, all designed with an anatomical shape to ensure minimal patient discomfort. • The resuscitator bag can be connected to a source of therapeutic oxygen and can be equipped with a reservoir to ensure optimal administration. • The use of this medical device is allowed only to authorized and appropriately trained persons.

2 WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

These operating instructions have been prepared using simple, easy to understand language. If you have difficulty interpreting what is written, please contact the manufacturer for further clarification.

Phone +39 0471 932893 **info@boscarol.it**

- Read these instructions carefully before using the device. Careful, correct use of the device ensures smooth operation and will protect both patients and operators.
- The use of this device is reserved for authorized and appropriately trained personnel. Training on how to position the face mask is advisable to obtain an optimal seal. Ensure that personnel are aware with the contents of this manual.
- The efficiency of ventilation must always be checked by observing the movement of the chest and listening to the expiratory flow coming out of the valve. If the ventilation is insufficient, immediately proceed to mouth-to-mouth respiration.
- Insufficient, reduced or no air flow can cause brain damage to the ventilated patient.
- The use of the PEEP valve can have negative effects such as barotraumas and/or reduced cardiac output. Only qualified medical personnel trained to use the PEEP valve should use the device supplied with the PEEP valve.
- 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 anaesthetic 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).
- The parts of the device must be disposed following national and local indications for the disposal of substances based on PVC, silicone, rubber.
- 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.
- Do not override the pressure-limiting valve (for pop-off models only) to prevent excessive ventilation pressures that may cause lung rupture on patients. However, if medical assessment indicates the necessity of overriding the pressure-limiting valve, a manometer must be used to monitor ventilatory pressure and avoid the possibility of lung rupture.
- 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.
- The device is not marketed sterile.

LATEX	The resuscitator bags and accessories are built and manufactured without the use of latex. However, the possibility that they may have come into contact with latex at some time during the production chain cannot be ruled out
CONTAMINATED DEVICE	Warning: Device contamination **THESE OPERATIONS ARE EXCLUSIVELY EXECUTABLE ON SILICONE REUSABLE DEVICES. CLEANING AND STERILIZATION OF DISPOSABLE DEVICES (PVC AND RUBBER) IS STRICTLY FORBIDDEN!** Contact with the patient during resuscitation may be a source of contamination. For this reason, after each use, the device must be cleaned and disinfected to eliminate any residual risk. Follow the instructions in this user manual.

	When in doubt, send an e-mail to the Boscarol technical service at info@boscarol.it or call +39 0471 932893
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 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. • If the devices or parts are disposable, they must be disposed of as a result of their use in accordance with national and local regulations.

3 INFORMATION THAT IS IMPORTANT TO KNOW BEFORE USE

The resuscitator bag has been designed and tested to meet the requirements of Directive 93/42/EEC concerning medical devices. Resuscitator bags and ventilation masks are medical devices of risk class IIa.

	If the user or patient becomes aware of a user hazard, a side effect, an accident caused by the device or a criticality (operational and constructive) not treated in these instructions for use, must immediately notify the manufacturer at the email address: info@boscarol.it
PERIODIC MAINTENANCE	**Periodic maintenance:** No parts/components of the device require particular periodic maintenance, except for standard functional verification operations as described in this manual. If defects, malfunctions or failed tests are detected, the device shall be removed and replaced by a new one. When in doubt, send an e-mail to the Boscarol technical service at info@boscarol.it or call +39 0471 932893.
LIFESPAN	Boscarol resuscitator bags and ventilation masks have a lifespan of **5 years** from the date of manufacture if stored and used in accordance with these operating instructions
Operator/User Responsibility	• Boscarol resuscitator bag is designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Immediately replace any damaged, altered or missing components/parts and/or those for which resuscitator bag malfunction is suspected. Always replace these parts with original spare parts. The resuscitator bag must be stored in a place that is out of the reach of children. • Dispose of packaging in accordance with applicable regulations and make certain it is out of the reach of children. • Tampering, alterations and modifications of the device are not permitted without the consent of the manufacturer.

4 CONTRAINDICATIONS (DO NOT USE FOR)

CONTRAINDICATIONS	• Resuscitation in rooms where the air is toxic or contaminated, in presence of explosives or where the air may be contaminated with anaesthetic agents. • Do not use the device on conscious people or without breathing difficulties. • Do not use a ventilation mask for a specific age group on a patient other than the recommended age group (such as adult mask used in infant patient or vice versa).

5 SIDE EFFECTS (POSSIBLE DURING ASPIRATION OPERATIONS)

SIDE EFFECTS	• Irritation and skin reactivity phenomena due to direct contact of the device on the patient face. • Passage of ventilated gases in the esophagus and stomach, especially in case of hyperextension of the neck. Gastric distention makes it difficult to expand the lungs and promotes regurgitation of gastric material in the esophagus and pharynx and subsequent inhalation in the tracheo-bronchial tree. • Damage to children's lungs due to excessive pressure of ventilation. • Brain damage to ventilated patient due to insufficient, reduced or no airflow. • Barotraumas and/or reduced cardiac output due to incorrect use of the device with PEEP valve.

6 OSCAR BOSCAROL RESUSCITATOR BAGS

After receiving the device, make sure that all parts are present (in case of complete resuscitator bag).

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 40 or 60 cmH_2O (392,24 Pa or 588,36 Pa), while child and neonatal ones at 40 cmH_2O (392,24 Pa). If necessary, the valve can be deactivated with a simple twist or pressure.

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 between 5 and 30 kg (11÷66 lbs)
Infant ventilation bag	For infant till 5 Kg (about 11 lbs)

7 OPERATING PRINCIPLE

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).

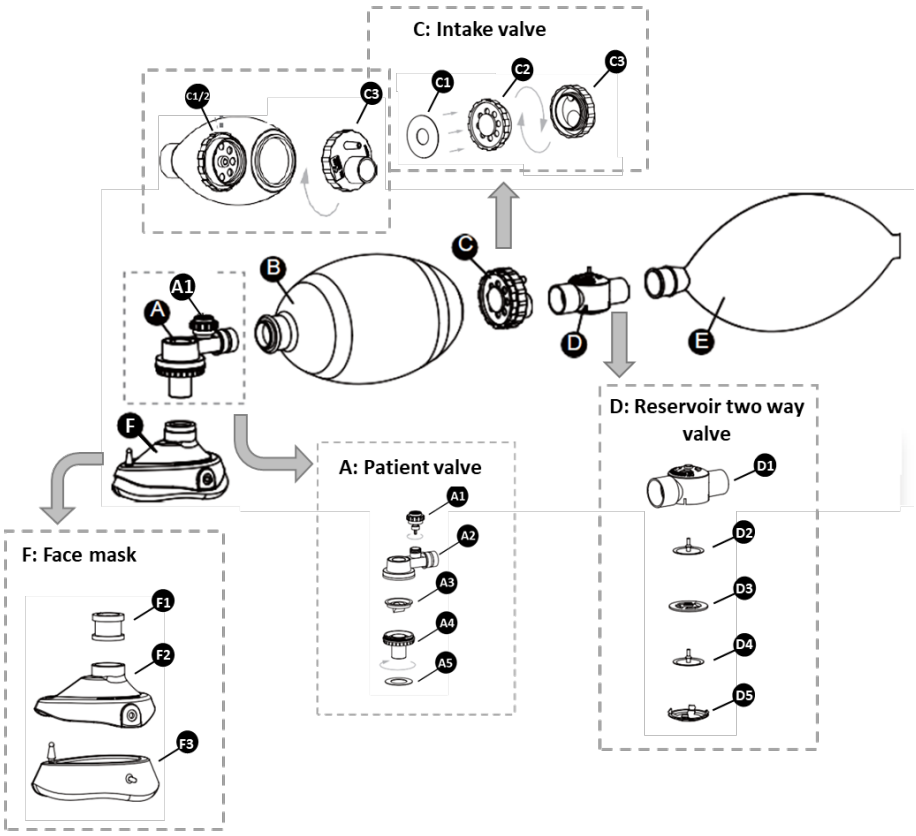
The patient's exhaled air cannot flow back to the resuscitator bag due to the non-return valve and thanks to a special mechanism it goes outside (to the ambient).

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!

8 CONFIGURATION OF THE DEVICE AND SPARE PARTS

8.1 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 "A1" is called "pop-off valve". The pop-off valve opens with pressures equal to or greater than 40 or 60 cmH_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.

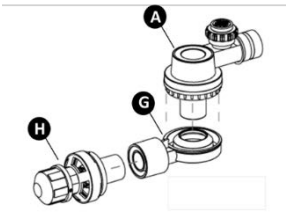


Ref No.	Description	Material
	A. Patient valve	
A1	Pop-off valve	Polycarbonate
A2	Upper patient valve	Polycarbonate
A3	One way valve	Silicone
A4	Lower Patient valve with mask connector	Polycarbonate
A5	Patient valve O ring	Silicone
	B. Resuscitator bag	
B	Resuscitator Bag with connector	Chosen material + Polycarbonate
	C. Intake valve	
C1	O ring intake valve	Silicone
C2	Upper body intake valve	Polycarbonate
C3	Lower body intake valve	Polycarbonate
	D. Reservoir two-way valve	
D1	Main unit two-way valve	Polycarbonate
D2	Upper O ring two-way valve	Silicone
D3	Upper O ring support two-way valve	Polycarbonate
D4	Lower O ring two-way valve	Silicone
D5	Lower cover two-way valve	Polycarbonate
	E. Reservoir bag with connector	
E	Reservoir bag with connector	PVC + Polycarbonate
	F. Face mask	
F1	Face Mask Connector	Silicone
F2	Face Mask Dome	Polycarbonate
F3	Face Mask seal	Chosen material + Polycarbonate

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.

8.1.1 PEEP positive pressure regulating valve (OPTIONAL)

The PEEP valve is designed for use with resuscitator bags. It provides positive pressure and exhalation pressure during ventilation. The use of the PEEP valve during ventilation does not affect inhalation resistance and oxygen concentration.



Ref No.	Description
A	Patient valve
G	Diverter
H	PEEP valve

8.2 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 cmH2O (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)**

8.3 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.

8.4 Optional accessories

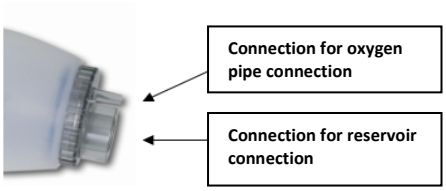
Auxiliary accessories for the device are available to facilitate the operations of emergency ventilation (e.g. helicoidal mouth/teeth opener, Guedel airway, oxygen tubes ready to use). Ask Oscar Boscarol srl for them.

9 USE OF THE DEVICE

9.1 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 right side).

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 picture on the left side).

9.2 Use of the PEEP valve

If you want to use the device with the PEEP valve, assemble the valve following the instructions below:

1. Clean and sterilise the valve regularly before each use.
2. Connect the diverter to the output of the patient valve.
3. Attach the appropriate PEEP valve.
4. Turn the PEEP valve knob to the appropriate pressure value indicated on the basis of the valve.

9.3 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 colour 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.

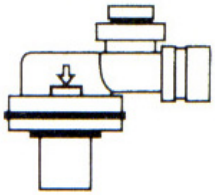
ATTENTION	After each use reusable devices must be decontaminated and/or sterilized, while disposable ones should be removed!

9.4 General instruction for use

1 Before starting with the ventilation, make sure that the patient is in stable and with face upward.
2 Verify that patient's mouth and upper airways are free of obstructions (liquid and solid substances).
3 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.
4 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.
5 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.
6 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

7 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.
8 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).
9 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.
10 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.).
11 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.



12 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.
13 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.

10 CLEANING AND STERILIZATION

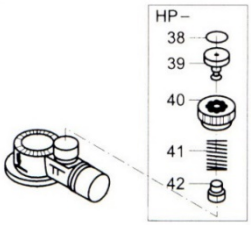
ATTENTION	**THESE OPERATIONS ARE EXCLUSIVELY EXECUTABLE ON SILICONE REUSABLE DEVICES. CLEANING AND STERILIZATION OF DISPOSABLE DEVICES IS STRICTLY FORBIDDEN!**

10.1 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.

10.1.1 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 figure reported on chapter 8.
6. Before using the device perform a functional test, as described in paragraph 11.

10.1.2 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 121°C (249.8°F) at a pressure of 1.1bar (= 110KPa ≒ 15.9psi), for 20 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.

After each process of sterilization (regardless of the type) it is necessary to wash all components under clean, lukewarm running water:

1. 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.
2. Reassemble the device according to the design of the previous page.
3. Perform a complete functional test as described in the next paragraph.
4. Keep the tested device in the nylon bag provided by purchasing.
5. Note on the packaging with a marker last performed sterilization.

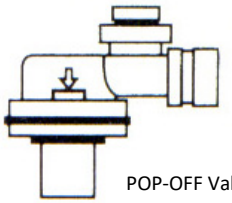
ATTENTION	The device can be sterilized and reused for 25 times. Once a maximum number of sterilisations of 30 times has been reached, the device shall be discarded. The manufacturer recommends performing accurate inspections on device surface after each operation of disinfection and/or sterilization!

11 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 above reported:

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°.



POP-OFF Valve

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

14 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 send an e-mail to the Boscarol technical service at info@boscarol.it or call +39 0471 932893.

15 TECHNICAL DATA AND CONFORMITY

Device conformity	
Device classification referred to Italian D. lg. 46/97 (MDD 93/42/CEE and subsequent amendments)	**IIa**
Power source	Ambient air or therapeutic oxygen (O2) at low pressure and controlled rate
Connection to O2 source	Directly to the device, through standard tube
Lifetime of the device	5 years from date of manufacturing
CE mark on the device	CE0123 (TÜV ITALIA srl)

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

Technical characteristics of the device	*Adult (> 30 kg)*	*Child (5÷30 Kg)*	*Infant (< 5 Kg)*
Bag Volume (ml)	1800	550	320
Stroke Volume (ml)	1060	320	140
Reservoir Bag (ml)	2700	2700	900
Expiratory/Inspiratory resistance	2.0 cmH2O/4.0 cmH2O		
Dead Space	Less than 7.0 ml		
Pressure relief (optional)	40 or 60 cmH2O	40 cmH2O	
Operating temperature	-18÷50 °C (test according to the EN ISO 10651-4:2009)		
Storage Temperature	15÷25 °C		

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

Connections	*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 1800ml – 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 550ml – Reservoir volume 2700ml*		
Flow O2	**(TIDAL) Delivered volume x ventilation rate**		
L/min	70x30	200x30	1000x12
5	83(32)	65(34)	55(31)
10	99(37)	99(37)	88(36)
15	97(46)	97(46)	97(44)

INFANT resuscitator bag

INFANT	*Ventilation bag volume 320ml – 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)

Device performance	*Adult (> 30 kg)*	*Child (5÷30 Kg)*	*Infant (< 5 Kg)*
Average volume for compression (ml)	900	250	130
Maximum loss	Less than 0,7 ml for all versions		
Resuscitator bag nominal volume (ml)	1778	478	305

Breathing resistance	*Adult (> 30 kg)*	*Child (5÷30 Kg)*	*Infant (< 5 Kg)*
Inspiration/exhalation	2,2 cmH2O (215 Pa) / 3,3 cmH2O (323 Pa) per 50 LPM	2,2 cmH2O (215 Pa) / 3,3 cmH2O (323 Pa) per 50 LPM	2,2 cmH2O (215 Pa) / 3,3 cmH2O (323 Pa) per 50 LPM
Exhalation final pressure (normal use conditions)	3,2 cmH2O (323 Pa)		
Pressure setting POP-OFF valve	40 cmH2O (3920 Pa) – manual block		
Unloading pressure of patient valve	138 cmH2O (13500 Pa)	101 cmH2O (9900 Pa)	87 cmH2O (8530 Pa)

Dimensions and weights (without accessories)	*Adult (> 30 kg)*	*Child (5÷30 Kg)*	*Infant (< 5 Kg)*
Dimensions and weights (without accessories)	325x130x130 mm – 314 gr. (±5 %)	255x91x91 mm – 194 gr. (±5 %)	256x85x74 mm – 158 gr. (±5 %)

16 WARRANTY

Oscar Boscarol guarantees the resuscitator bag (all variants) for a period of 1 year from the date of purchase from the original distributor. The company guarantees that the device is free of material and/or manufacturing defects.

The warranty does not cover: the normal wear, discoloration and any other cosmetic irregularities that do not affect unit operation.

If, at any time during the entire 1-year warranty period, the product is found to be defective, before sending the device must be sent to Oscar Boscarol srl a specific request for authorization to return. In case of acceptance of the return, the Oscar Boscarol Srl (Ltd) will repair or replace the defective parts and/or the whole unit at its own discretion. All shipping costs are charged to the customer.

Warranty conditions:

To benefit from the warranty, the registration form found in the product documentation must be filled out and returned by mail, fax or e-mail to the following address:

OSCAR BOSCAROL SRL V. E. Ferrari, 29 – 39100 BOLZANO, ITALY

Fax: +39 0257760142 – E-mail: production.manager@boscarol.it

To validate the warranty process, the customer must provide evidence of the following documentation:

5. copy of the invoice and/or receipt of purchase containing the device serial number and date of purchase.
6. confirmation from the manufacturer or its representative that it really does involve a fault stemming from the manufacturing process or components deemed defective from the time of their supply.
7. absence of any tampering, changes and/or anything that does not conform with the original product.

In terms of safety, reliability and functionality of the device, Oscar Boscarol S.r.l. can be held responsible only if the device has been and is used correctly, strictly following the directions provided in these operating instructions.

With reference to what is described in these warranty conditions, Oscar Boscarol S.r.l. cannot be held liable for direct or indirect accidental damage, if modifications have been made to the device or any of its parts have been damaged by accident and misuse. On the resuscitator bag there are no other express or limited warranties of merchantability, fitness or or other outside those described in this manual.

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