User's Manual

B-Bag
Double wall resuscitation bag

CE 0123

This appliance conforms with the directive 93/42/CEE "Medical Devices"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GMBH

INDEX

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Thank you for choosing a Spencer product.

1 GENERAL INFORMATION

1.1 AIM AND CONTENTS

The aim of this manual is to supply all the information necessary so that the client, apart from attaining an adequate use of the appliance, will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 CONSERVATION OF THE INSTRUCTION MANUAL

The instruction and maintenance manual must be kept with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 SYMBOLS USED

SYMBOL	MEANING
	See instructions for use

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on 0039 0521 541111 - Fax 0039 0521 541222 e-mail: info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY.

1.5 DEMOLITION

In conformity with current regulations.

2 WARNINGS

2.1 GENERAL WARNINGS

- Before carrying out any kind of operation on the appliance, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia Srl, for any necessary clarifications.
- Regularly check the appliance. Carry out the prescribed maintenance in order to keep the appliance in good condition and to guarantee correct functioning and a long life.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning, and the safety, the appliance must be immediately removed from service.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with, in such cases all responsibility will be denied for any malfunctions or eventual injuries caused by the appliance itself.
- Who modifies or has modified, prepares or has prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Ensure that all the necessary precautions are taken in order to avoid hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

2.2 SPECIFIC WARNINGS

- The B-BAG manual resuscitator must be used only by operators who have been adequately trained in the techniques of cardio- pulmonary resuscitation (CPR o ACLS).
- The device should not come into contact or be in any way exposed to sources of heat or inflammable agents.
- The administration of oxygen in the presence of hydrocarbons will generate an explosive mix.
- Do not use the device in a contaminated atmosphere.
- Do not administrate or enrich with oxygen in the presence of fire or sparks.
- Remove the reservoir if enrichment with oxygen is not necessary.
- Do not use lubricants (ex. oils or grease) on any part of the manual resuscitator.
- Check the state of the products on opening the product and before each use.
- Do not dismantle the overpressure valve.
- The device contains latex and may cause anaphylactic shock in subjects allergic to that substance.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

The use of this device, if used by operators who have been adequately trained in the techniques of cardio-pulmonary resuscitation (CPR o ACLS) does not present any particular hazard.

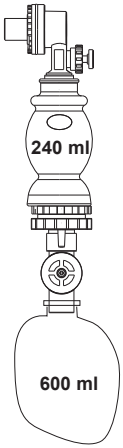
3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

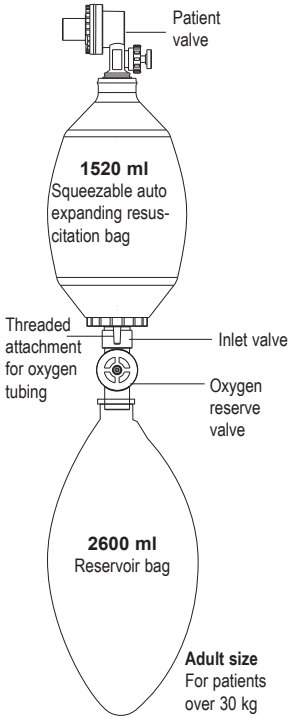
The B-BAG manual resuscitators have been designed to offer adequate assistance to patients during the CPR and assisted ventilation manoeuvres.
They can be used efficiently and safely to maintain pulmonary ventilation in case of reanimation and in other critical situations when spontaneous respiration is insufficient or absent.
The B-BAG manual resuscitators can be used to supply oxygen when connected to a source of oxygen. In order to guarantee a high percentage of oxygen, the manual resuscitator is supplied complete with a valve and reservoir.
The percentage of oxygen supplied to the patient depends on:
• flow
• current volume
• frequency
• technique being used
The device contains latex and may cause anaphylactic shock in subjects allergic to that substance.

3.2 MAIN COMPONENTS

The B-BAG manual resuscitators are available in two sizes:
• adult
• infant



Infant
For patients under 7 kg



Adult size
For patients over 30 kg

3.3 MODELS

BG07030B	B-BAG adult with overpressure valve

3.4 TECHNICAL DATA

Resuscitation bag		B-BAG	
Part		Infant	Adult
Bag		Rubber	Rubber
Membrane valve		Rubber	Rubber
Reservoir		PVC	PVC
Overpressure valve spring		Stainless steel	Stainless steel
Patient valve		PE	PE
Suction valve		PE	PE
Reservoir valve		Polycarbonate	Polycarbonate
Overpressure valve		PE	PE
Nominal volume (ml)	bag	280	1520
	reservoir	600	2600
Dead space (ml)		7	7
Overpressure valve insertion (mbar)		40 +/- 5	60 +/- 5
Packaging		Not sterile	Not sterile
Max. volume per cycle (ml)		130	900
Max. re expansion rhythm (bpm)		95	45

Concentration of oxygen possible: ADULT						
Resuscitation bag volume: 1520 ml				Reservoir volume: 2600 ml		
O_2 Flow	Current volume (ml) for re expansion rhythm of bag/min Concentration of O_2 with reservoir					
(L/m)	600 x 12	600 x 20	750 x 12	750 x 20	1000 x 12	1000 x 20
05	82 (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)

Concentration of oxygen possible: INFANT				
Resuscitation bag volume: 280 ml			Reservoir volume:: 600 ml	
O_2 Flow	Current volume (ml) for re expansion rhythm of bag/min Concentration of O_2 with reservoir			
(L/m)	20 x 30	20 x 60	40 x 60	70 x 60
05	97 (75)	97 (72)	97 (59)	85 (52)
10	97 (75)	97 (78)	97 (78)	86 (61)
15	97 (95)	97 (92)	97 (82)	97 (73)

3.5 ENVIRONMENTAL CONDITIONS

Temperature of use (°C)	from 0 to +50
Temperature for stocking and transport (°C)	from -20 to +50

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks or falls during the transport itself.
Keep the original packaging for any eventual further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the Client. The appliance must be stored in a dry place free from humidity.

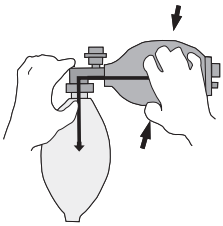
4.2 PREPARATION

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.

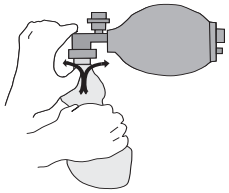
4.3 FUNCTIONING TEST

Once assembly has been completed (after the cleaning process) or before each use, the following functions should be tested.

• Patient Valve Test

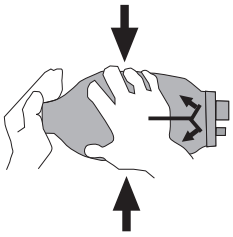


The reservoir should be used for this test:
•Connect patient valve to bag.
•Connect reservoir to patient valve.
•Repeatedly squeeze the bag and check that the reservoir continues to fill and make sure that the air being pumped in is passing through the patient valve in the correct direction.

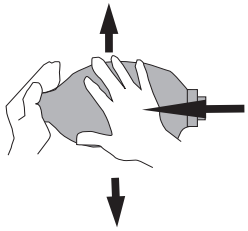


•Using the palm of the hand, squeeze the reservoir and check that the circular membrane on the outer side of the patient valve opens up.
• This procedure checks the flow of air expelled by the patient and avoids it returning into the bag through the patient valve and single direction flow is maintained.

• Suction Valve Test

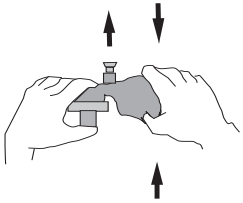


•Squeeze the bag with your hand.
•Close off the opening at the neck of the bag.
•Release the bag. The rapid expansion of the bags, ensures the correct suction/intake of air.
•Using the palm close the opening on the neck of the bag.



•Squeeze the bag. The correct resistance to compression confirms the correct functioning of the suction valve during the insufflation phase.

• Overpressure valve test



•Close the exit of the patient valve.
•Strongly squeeze the bag several times and test as follows:
In "Adult" mode, the hand should feel adequate resistance and no air should come out of the Overpressure valve; in "Infant" position the air should come out of the valve making an audible sound.

4.4 USE

• Make sure the patient is in a safe place and position the mask over the patient's face and nose and hold it in place with index finger and thumb.

• Using the other hand, ventilate the patient by squeezing rhythmically the bag, as prescribed by your standard area protocols.

Check that the patient's chest expands during the ventilation phrase (squeezing of the bag) and that it contracts during the following expiring phrase (the bag expands). Observe the patient's colour and the colour of the lips. Use a mask that covers both nose and mouth correctly (which means that the area from the top of the nose to the bottom lip is covered by the mask excluding the chin which must remain uncovered) After choosing the mask, assemble onto the resuscitation bag. Check that the parts are all correctly assembled. If necessary, free the airways of any liquid, vomit or foreign bodies which could be obstructing them. Taking the necessary care - hyper extend the patient's neck. The manual resuscitator can be connected to a source of oxygen (fixed or mobile).

The gas supplied to the patient can be enriched with oxygen:

• Connect a no crush oxygen tube between the connection on the reservoir valve and the flowmeter of the oxygen cylin der or central oxygen supply.

• Regulate the flow so that during the insufflation phrase (patient inspiring) the reservoir fills up completely and it collapses during the expiratory phrase.

• If enrichment with oxygen is not required and/or there is no source of oxygen, remove the reservoir.

• On attaching the resuscitator to the oxygen source make sure that the reservoir expands.

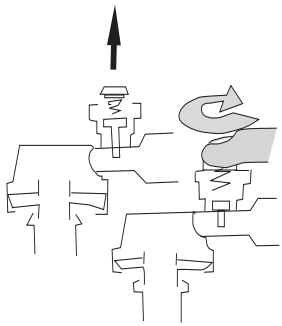
• In a contaminated atmosphere, use only oxygen for patient reanimation.

• The condition of the patient must always be under constant control.
To select the Overpressure valve valve, (if included) press and turn (as indicated in the diagram).

• Should the overpressure valve become contaminated with blood, vomit or any type of secretion, remove the resuscitator from use and continue to ventilate the patient with the aid of a single direction mouth to mouth mask/valve.

• Before using a mouth to mouth valve we advise to disconnect the resuscitator from the patient and strongly squeeze the resuscitator to remove any liquid from the patient valve.

• Check that the valve is clean and in this case continue to ventilate with the resuscitation bag.
On terminating resuscitation, clean and sterilize (where possible) and test the device as described in this manual.



4.5 TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
The chest does not expand correctly during ventilation	Obstructions of the airways caused by foreign bodies	Free the airways by manually removing any foreign bodies
	The head is not correctly extended	Place the patients head in the correct position
	The mask does not adhere perfectly to the patients face	Reposition the mask following the instructions and press slightly to improve adherence
	Air leakage from components of the resuscitation bag	Check that all components of the resuscitator are correctly assembled together
	One of components is damaged	Immediately remove the device from service and contact your Assistance Centre
The mask leaks air even though correctly positioned	The patient has moustache/beard or his skin is sweaty	If the face is sweaty try to clean and dry face. In the case of beard or moustache, increase the pressure on the mask

5 MAINTENANCE AND CLEANING

5.1 CLEANING

During cleaning and assembly of the device, Personal Protection Equipment (PPE) should be used.

Washing the resuscitator.

After use, clean and disinfect the B-BAG resuscitator as follows.

Dismantle the resuscitator from the mask and wash all parts with water and a mild detergent. Make sure that the detergent is compatible with the material of the resuscitator. Rinse under running warm water making sure to remove all traces of detergent.

Do not remove the overpressure valve as it could cause permanent damage.

The reservoir is a single use product and cannot be sterilized. Dispose after use.

Boiling for 6 minutes	No
Autoclave maximum as Rif.UNI EN 554	No
Autoclave rubber cycle as Rif.UNI EN 554	No
Ethylene oxide Rif.UNI EN 550	No
Liquid sterilizer	Yes

Failure to carry out correctly the cleaning procedure, could be a cause of cross infection due to the presence of secretions and/or residuals on the device.

5.2 Precautionary Maintenance

The device is not subject to a periodical service routine.

5.3 Servicing Maintenance

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

The device, if used as described in the following instructions, has a life span of 5 years.

6 ACCESSORIES, SPARE PARTS AND CONFIGURATIONS

Spencer Mask polysulfonate black size 0 soft	RM20400A
Spencer Mask polysulfonate black size 0	RM20800A
Spencer Mask polysulfonate black size 2	RM20802A
Spencer Mask polysulfonate black size 4	RM20804A
Spencer Mask polysulfonate black size 5	RM20805A
Spencer Mask Kit four sizes polysulfonate black	RM20810B
Spencer Mask polycarbonate black size 0 soft	RM20400A
Spencer Mask polycarbonate black size 0	RM20700A
Spencer Mask polycarbonate black size 2	RM20702A
Spencer Mask polycarbonate black size 4	RM20704A
Spencer Mask polycarbonate black size 5	RM20705A
Spencer Mask Kit four sizes polycarbonate black	RM20710B
Spencer Mask polycarbonate blue size 0 soft	RM20400A
Spencer Mask polycarbonate blue size 0	RM20900A
Spencer Mask polycarbonate blue size 2	RM20902A
Spencer Mask polycarbonate blue size 4	RM20904A
Spencer Mask polycarbonate blue size 5	RM20905A
Spencer Mask polycarbonate blue Kit four sizes	RM20910B
EVX 12 Patient valve autoclavable	EV50012C
EVX 10 Patient valve single use	EV50010C
EVX 07 Patient valve autoclavable ped./infant 40 cmH2O	EV50007C
EVX 08 Patient valve single use ped./infant 40 cmH2O	EV50008C
EVX 09 Patient valve single use adult 60 cmH2O	EV50009C
EVX 11 Patient valve autoclavable adult 60 cmH2O	EV50011C
Reservoir bag with valve per adult B-BAG	BG07002B
Reservoir tube for Infant B-BAG	BG07003B
Bottom hub cab with screw for adult B-BAG	BG07004B