User's Manual

B-Vac
Manual aspirator for secretions

CE This appliance conforms with the Directive 93/42/CEE "Medical Devices" and with the technical norm EN ISO 10079-2.

Guarantee of Quality System for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH.

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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, will not only attain adequate use of the appliance, he 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 together with the product, for the whole life of the device, 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
	General or specific warning
	See instructions for use
	Lot number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE
	Single use

1.4 Servicing requests

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 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. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

Follow the current regulations.
When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

1.6 Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the Manufacturer, the product, CE mark, lot number (LOT). It must never be removed or covered.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Before carrying out any kind of operation on the appliance (training, installation, use), 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.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.

- 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 (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have 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.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Use of the device in anyway other than described in this manual is forbidden.
- Handle with care.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations. In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users o any medical device.

2.2 Specific warnings

- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Never leave the patient unassisted, because he may be injured.
- Some components of the device are disposable, for use with one patient. They cannot be washed or re-sterilized after use. Reuse can cause cross-infection. They can not be used after the expiry date stated on the packaging of the device.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport device in its original packaging.
- The aspiration must be carried out in strict accordance with the appropriate procedure established by a recognised medical authority.
- Some accessories may not be suitable for the tubes that are supplied. All accessories must be checked before use to ensure that they are suitable for the apparatus.
- The use of the apparatus may require the appropriate precautions against infectious diseases, both during the use and the cleaning or during the connection of the tube and the jar.
- The user must carry out the Test, as described in paragraph 4.3, after dismantling and re-assembling the apparatus.

2.3 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

B-Vac is a portable suction pump that has been studied especially for the collecting of non-inflammable liquids substances, for use exclusively for medical purposes. It is used for a fast, safe and efficient clearing of patients' airways. It is easy to use and is particularly suitable for use in emergency situations; it does not require any power source and can be used with only one hand. The appliance has been designed in order to allow for a good use, even in difficult situations and to avoid the premature activation of the over flow mechanism.

B-Vac is equipped with a 3M™ HEP filter, inserted into the lid of the collecting jar to inhibit any bacterial or viral contamination of the rescuer during use.

There is a switch on the posterior part of the appliance, which allows the rescuer to regulate the aspiration so that it can function at 100% for adults and at 50% for a paediatric use.

3.2 Main components

From a functional point of view, the appliance is composed of the following main components:

1. Suction catheters
2. Jar
3. Anti bacteria filter
   3.1 Overflow valve
4. Support handle and lever for activating the suction pump
5. Two-position switch for suction

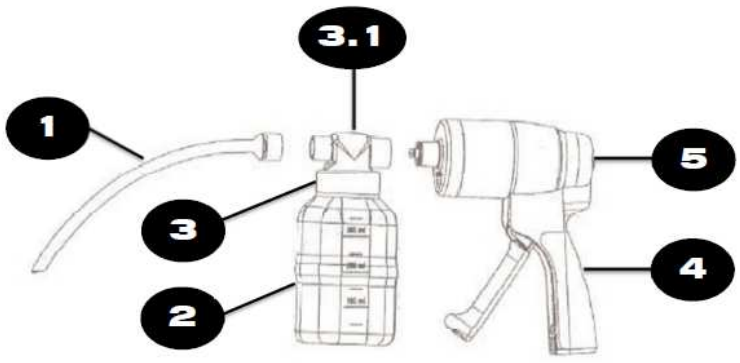

Fig. A

CATHETER: single use device, not reusable, allows for the channelling of the secretions into the collecting jar.

COLLECTING JAR: single use device, not reusable, allows for suction and collection of substances aspirated via the suction catheter.

ANTI-BACTERIA FILTER: single use device, not reusable, impedes any bacterial or viral contamination of the rescuer during use.

OVERFLOW VALVE: single use device, not reusable, by closing automatically when the maximum capacity of the jar is reached, it is guaranteed that the collected liquids cannot infiltrate the internal parts of the suction pump. When the jar is full, the valve closes thus creating, in the case of any attempt to turn on the appliance again, an elevated power of resistance.

HANDLE FOR ACTIVATING SUCTION: allows the appliance to be used with one hand only.

DUAL POSITION SWITCH: allows the rescuer to regulate the suction to 100% for adult and to 50% for a paediatric use.

There are also systems that regulate the overflow of the system. They do not allow the leakage of the secretions even if used in a perpendicular position or turned upside-down.

3.3 Models

These basic models could be modified, with reference to codes and/or descriptions without any previous notification.

B-Vac	RV71150

3.4 Technical data

Dimensions when assembled, including suction catheter	400 x 170 x 80 mm
Dimensions when packaged	205 x 180 x 85 mm
External diameter of catheter	Ø 18 mm Ø 9 mm
Diameter of catheter connection	Ø 17 mm
Efficiency of bacteria filtration	99,99%
Efficiency of viral filtration	99,99%
Weight of packaged appliance	420 g
Weight of appliance	290 g
Maximum vacuum	-550 mmHg
Capacity	>20 l/min
Capacity of jar	350 ml

3.5 Environmental conditions

During functioning:
Temperature from -20 to +50 °C
Relative humidity from 5 to 90%
During storage:
Temperature from -40 to +60 °C
Relative humidity from 5 to 90%

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, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. 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 device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics. Prevent the device from bumps and vibrations.

4.2 Preparation

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.
1.Select the size of the suction catheter and connector depending on the age of the patient. Set the suction switch at 100% for adults and at 50% for children and newborn infants.
2.Connect the connecting suction catheter to the lid of the jar. Connect the handle to the lid of the jar. Inversion of the connection of the tubes could cause irreparable damage to the appliance.
3.Check that the jar is firmly attached to the upper part of the jar and that every connection is both correct and firm.

4.3 Functioning

Turning on

1. The appliance is turned on by simply pulling the lever towards the handle of the suction pump, to create the vacuum inside the appliance itself. The liquid will enter the colecting jar. It is possible to check the appliance by immersing the suction tube in a container full of water; this test allows for a more accurate evaluation of the actual suction capacity in relation also to the volume. The appliance is equipped with a protection system that helps to avoid infiltration of the liquids collected inside the appliance when saturation point of the jar is reached. This system does not allow for suction to continue as it becomes impossible to pull the handle of the suction pump. It is advisable to have at hand a replacement jar in order to guarantee the continuity of the suction operation and to allow for the cleaning of the jar in use.
2. Once suction is terminated, slowly remove the tube from the patient.
3. Remove the collecting jar and the catheter from the handle of the suction pump.
4. Place the jar and the tube in a bag.

It is important to check that the suction pump works every time after it has been dismantled and re-assembled and before every use. To assemble a jar: with either the thumb or palm of the hand, block the connection point of the lid and compress in order to verify the vacuum.

After use
When use of the appliance is terminated, disconnect the tube, replace the disposable parts and carry out thorough cleaning (see paragraph 5), then put away the suction pump correctly.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Lack of suction	Incorrect connection of the suction catheter	Connect the suction catheter correctly
	Obstruction of the catheter	Replace the catheter
	Severing of the catheter	Replace the catheter
	The collecting jar does not create the vacuum	Adjust and/or screw the lid. If the problem persists, contact the Service Centre
	Use of the handle does not create vacuum	Contact the Service Centre

5. MAINTENANCE AND CLEANING

5.1 Cleaning
The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.
Failure to carry out the correct cleaning routine could increase the risk of cross infection.

In order to maintain the appliance in a good condition the following operations should be periodically carried out:
5.1.1Cleaning of the handle
Clean the handle with a clean cloth and with any of the disinfectants available on the market (bactericide-germicide).
The suction pump must never be immersed in water or any other solutions.
The collection jar, the cap containing the filter, the valve and the catheter must be replaced after each use.

5.2 Maintenance
5.2.1 Precautionary maintenance
The person who carries out the precautionary maintenance of the appliance (control activity described on paragraph 4.2) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

The person who is provided routine maintenance can replace only the parts listed in paragraph 6.2 “Spare parts”. For other activities to replace/repair contact themanufacturer or an authorized by him.

The device does not require periodic review of the planned interventions by the Manufacturer.

5.3 Special maintenance and average life span
The maintenance can be performed only by the Manufacturer or authorized service centers approved by the Manufacturer.
The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the Manufacturer or by a centre authorised by the Manufacturer.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

There aren't any accessories for this item.

6.2 Spare parts

RV71151	Kit jar with spare tubes
RV71154	Spare jar
RV71155	Spare aspirator body
RV71152	PVC tube crystal Ø 16x22 mm
RV71153	Spare tubes