User's Manual

# JET COMPACT / JET WIRE

Portable suction unit

**Jet Compact**

**Jet Wire**

**INDEX**




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**Distributed by:**


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## 1. GENERAL INFORMATION

### 1.1 Aim and contents

The aim of this instruction guide is to supply all the information necessary so that the client, will not only attain adequate use of the device, he will also be capable of using the device 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 guide must be kept together with the device, for the whole life of the device, inside the specially provided container and above all, away from any substances or liquids which could cause damage to the device.

### 1.3 Symbols used

| Symbol | Meaning |
|---|---|
|  | General or specific warning |
|  | Consult instructions for use |
| SN | Serial Number |
| REF | Catalogue number |
| CE 0044 | The product is compliant with the specifications of the Directive 93/42/CEE |
|  | Type BF applied part |
| ~ | Alternating current |
|  | Direct current |
| | Single Use |
|  | Standby – on/off |
|  | Center positive polarity indicator |
|  | IP12: Vertically falling water drops shall have no harmful effects when the enclosure is tilted at an angle up to 15° on either side of the vertical. |
|  | The device contains electrical and/or electronic equipment that must be recycled per EC Directive 2002/96/EC - Waste Electrical and Electronic Equipment (WEEE) |

### 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 service@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) shown on the label applied on the box or on the device.

### 1.5 Demolition

**Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes"**.

The crossed dustbin symbol applied on the product or on its packaging indicates that the item should be disposed of separately. The correct disposal of the item when use has terminated, is defined and organised by the manufacturer.

The end user who has to proceed with disposal, must therefore contact the manufacturer and follow the system and procedures the manufacturer has organised for the separate collection, treatment and disposal at end-of-life. The correct separate collection of the out of use device which will permit recycling, treatment and destruction in an ecologically friendly manner and will contribute to avoiding possible negative effects on the environment and for health while privileging the reuse

and/or recycling of the collected waste components. Please note that the owner will be subject to administrative sanctions in case of unauthorised disposal of the item.

**DISPOSAL OF WASTE BATTERIES - (Directive 2006/66/CE) (if present)**

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste. By ensuring these batteries are disposed of correctly, you will help prevent potentially negative consequences for the environment and human health which could otherwise be caused by inappropriate waste handling of the

battery. The recycling of the materials will help to conserve natural resources. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, your household waste disposal service or the shop where you purchased the product.

### 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, serial number (SN). 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.
- 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 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.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on 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 or Spencer Italia S.r.l. immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact the Manufacturer or Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained persons to help during the use of the device, because they could cause injury or harm to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and sure what is meant here for this part, as indicated by the Manufacturer in this User's Manual.
- 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 or Spencer Italia S.r.l. must be contacted.
- 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.
- Use of the device in anyway other than described in this manual is forbidden.
- Do not alter or modify the device in any way; any such modifications 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.
- Handle with care.
- 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.
- 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.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.

- 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 notably different from results to the obtained data. Instructions are continually being updated and are under tight surveillance of fully qualified staff with adequate technical formation.
- 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 of any medical device.
- As a Distributor or End User of products marketed by Spencer Italia S.r.l., you are strictly required to have a good knowledge of any legal requirements valid in the final destination Coutry, applicable to the supplied devices (including laws and norms regarding technical specifications and/or safety requirements) and therefore you are also strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the territory regulations.
- Promptly notify Spencer Italia S.r.l. regarding any revisions to be made by Manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodic checks on their devices, as specified in the relevant instruction guide.
- Actively conduct periodic safety checks on devices sold, by communicating any relevant risk analysis information both to the Manufacturer and to any competent authorities so that the necessary action can be promptly taken.
- That said, the Distributor or End user, assumes from now the broadest liability relating to failure to fulfill the above obligations with obligation to indemnify and/or hold harmless Spencer Italy S.r.l. from any prejudicial effect.

### 2.2 Specific warnings

- Do not place or store product where it can fall or be pulled into a tub or sink and come in contact with water.
- Do not place in or drop into water or other liquid.
- Do not reach for a product that has fallen into water. Unplug the mains supply cable immediately.
- To reduce the risk of burns, electrocution, fire or injury to persons, close supervision is necessary when this product is used by, on, or near children or physically challenged.
- Use this product only for its intended use as described in this guide.
- Never operate this product if has a damaged power cord or plug, Return the product to an authorized Spencer Italia S.r.l. Service Center for evaluation and repair.
- Never operate this product if is not working properly, Return the product to an authorized Spencer Italia S.r.l. Service Center for evaluation and repair.
- Never operate this product if has been dropped or damaged, Return the product to an authorized Spencer Italia S.r.l. Service Center for evaluation and repair.
- Never operate this product if has been dropped into water, Return the product to an authorized Spencer Italia Srl Service Center for evaluation and repair.
- Keep the power cord away from heated surfaces.
- This suction unit is a vacuum suction device designed for the collection of nonflammable fluid materials in medical applications only.
- Improper use during medical applications can cause injury or death.
- All suctioning should be done in strict accordance with appropriate procedures that have been established by a licensed medical authority.
- Some attachments or accessories may not fit the tubing supplied.
- All attachments or accessories should be checked prior to use to assure proper fit.
- Do not use equipment in the presence of a flammable or anesthetic gas mixture.
- If either unit is operated off vertical or on an uneven surface, the collection canister overflow shutoff may activate prematurely, shutting off suction before canister achieves full capacity. Always have a spare replacement canister readily available.
- Do not attempt to connect any type of suction tubing directly into the vacuum inlet port.
- Only use with a canister approved by the Manufacturer.
- Always have a spare 300 ml canister within reach in case the canister in use is full or the filter becomes wet.

### 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

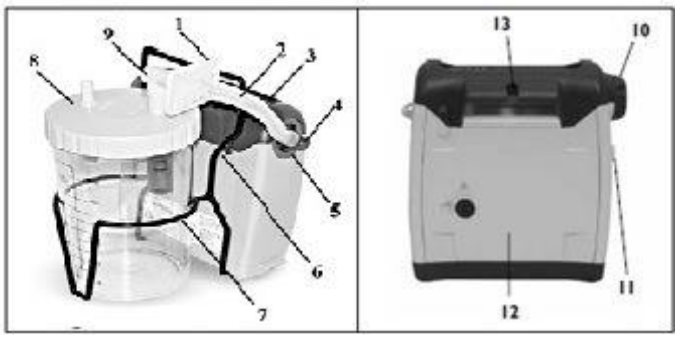
Jet Compact / Jet Wire is a compact medical suctioning device designed for reliable, portable operation. The device is to be used to remove fluids from the airway or respiratory support system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal.

This suction unit is ideal for providing emergency suction in the field, transport, and hospital environment. Two collection container options include the 1000 ml reusable canister and the 300 ml singleuse sealed disposable canister. To maximize product life and performance, follow recommended operating and maintenance procedures.

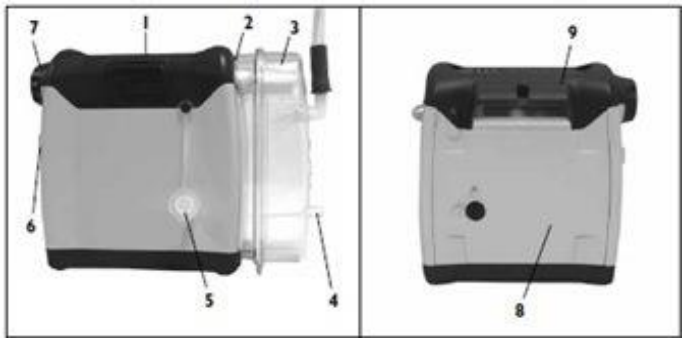
### 3.2 Main components

| n° | Description of component (fig. A) |
|---|---|
| 1 | Bacteria Filter |
| 2 | Connection Tubing |
| 3 | Display Panel (top of unit) |
| 4 | Unit Connection Elbow (for use w/ 1000 ml) |
| 5 | Vacuum Inlet Port (side) |
| 6 | Tethered Plug |
| 7 | Wire Canister Bracket |
| 8 | 1000 ml Disposable Canister with Lid |
| 9 | 90° Canister Connection Elbow |
| 10 | Vacuum Regulator Knob (on side) |
| 11 | DC Power Input (on side) |
| 12 | Battery Door |
| 13 | Unit Carry Handle/Catheter Holder |
| 14 | 1,8 m Patient Tubing (not shown) |
| 15 | Power supply cable 12 V (not shown) |
| 16 | High Capacity Rechargeable Battery (not shown) |

| n° | Description of component (fig. B) |
|---|---|
| 1 | Display Panel (top of unit) |
| 2 | Vacuum Inlet Port (side) |
| 3 | 300 ml Disposable Canister with 0.9 m (3') Patient Tubing and Internal Bacteria Filter/Fluid Shut-off |
| 4 | Canister Tubing Fitting for Disposal |
| 5 | Tethered Plug |
| 6 | 12V DC Power Input (on side) |
| 7 | Vacuum Regulator Knob |
| 8 | Battery Door |
| 9 | Unit Carry Handle/Catheter Holder |
| 10 | Power supply cable 12 V (not shown) |
| 11 | High Capacity Rechargeable Battery (not shown), 12V DC Ni-MH |




**Jet Wire (Fig. A)**




**Jet Compat (Fig. B)**

### 3.3 Models

**This model could be modified, with reference to codes and/or descriptions without any previous notification.**

SC75100B Jet Compact
SC75400B Jet Wire w/canister 1000 ml reusable

### 3.4 Technical data

| Characteristics | SC75100B | SC75400B |
|---|---|---|
| Dimension | 18x27x8 cm | 22x20x23 cm |
| Weight | 1,6 kg | 1,8 kg |
| Electrical Requirements | 100-240 VAC 47/-63 Hz 0,75 A max; 12VDC 33W max | |
| Internal Rechargeable Battery | 12 VDC | |
| Vacuum Range | from 50 to 550 mm Hg (±27,5 mm Hg) | |
| Air Flow | 32 lpm | |
| Collection Canister Capacity | 300 ml single use | 1000 ml reusable |
| Mode of Operation | 30 min ON, 30 min OFF | |
| Degree of protection against ingress of liquids | IP12 and standard power supply | |
| With respect to protection from electric shock | Class I and internally powered | |
| Degree of protection against electric shock | Type BF Applied Parts | |
| ISO Classification10079-1:1999 | High Flow/High Vacuum | |
| Directive 93/42/CE classification | IIa | |

### 3.5 Reference standards

| Reference | Title of document |
|---|---|
| MDD 93/42/CEE | European Directive about Medical Devices |
| MDD 2007/47/CEE | Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market |
| Legislative Decree 24/02/1997, n. 46 | Application of the 93/42/CEE Directive about Medical Devices |
| Legislative Decree 25/01/2010, n. 35 | Modifications and additions to the 20/02/97 Decree n. 46 |
| ISO 10079-1 | Suction device for medical use. Electric operated suction device. Safety requirements. |
| IEC 60601-1 + A1 + A2 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2 + A1 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| CAN/CSA 22.2 No.601.1-M90 | Electro medical devices - General Safety norms - Canadian standards. |
| UL 2601-1 | Safety requirements for electromedical devices |
| UNI EN ISO 14971 | Medical devices -- Application of risk management to medical devices |
| IEC 68-2-27 | Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock |
| IEC 68-2-6 | Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal) and guidance |
| IEC 68-2-64 | Environmental testing - Part 2: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance |
| RTCA/DO-160E, Section 21 Category M (only for battery powered ) Commerical airlines, airline equipment | "Enviromental Conditions and Test Procedures for Airborne Equipment - Section 21: Emission of Radio Frequency Energy |

### 3.6 Environmental conditions

| | |
|---|---|
| Operating Temperature Range | from 0 to 45 °C |
| Operating Relative Humidity | from 0 to 95% |
| Operating Atmospheric Pressure | from 70 kPA to 106 kPA |
| Storage & Transport Temperature Range | from -40 to 70 °C |
| Storage & Transport Relative Humidity | from 0 to 95% |
| Storage & Transport Atmospheric Pressure | from 50 kPA to 106 kPA |

## 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.

### 4.2 Preparation

#### 4.2.1 Battery connection

**All models of Jet are shipped with the battery in place but not connected.**

Follow the instructions below:

1. Using a coin or straight-blade screwdriver rotate latch to unlocked position (fig. 1).
2. Remove door by pulling up on latch (fig. 2).
3. Remove battery from compartment and plug connector into circuit board (fig. 3).
4. Replace battery and door; rotate latch to locked position.
5. Fully charge battery for 5 hours before using (please see battery charging).


Figura 1


Figura 2


Figura 3

#### 4.2.2 Canister connection (configuration 1000 ml)

1. Place canister into wire canister bracket; ensure inlet port marked <Patient> is accessible.
2. Attach one end of the connection tubing to connection elbow (fig. 4).
3. Insert unit connection elbow into side port (fig. 5).
4. Attach other end of connection tubing to side of filter marked <Out>.

**Use only Spencer supplied replacement filters (fig. 6).**

5. The 90° canister elbow connects to the clear side of filter marked <In> and to the top of canister lid marked <Vacuum> (fig 6).

**Verify clear side of filter marked <In> faces canister.**

6. Connect the 1.8 m (6') patient tubing to canister lid at inlet port labeled <Patient>.
7. Ensure all connections are secure to prevent leakage in the canister/tubing system.
8. Occlude the suction tube and set suction level according to local protocol before suctioning the patient (fig 7). Be aware that it might be necessary to adjust the suction level during use.


Figura 4


Figura 5


Figura 6


Figura 7

#### 4.2.3 Canister connection (configuration 300 ml)

1. This single-use sealed canister includes an internal filter and fluid shut-off that automatically stops suctioning when it becomes wet (fig. 8).
2. Firmly attach canister by pushing connection fitting straight into the open side port of unit. (Both the top connection fitting and the bottom support tab secure the canister) (fig. 9).
3. Securely attach appropriate suction tip to the tubing.
4. Occlude the suction tube and set suction level according to local protocol before suctioning the patient (fig. 7). Be aware that it might be necessary to adjust the suction level during use.

**While suction unit will continue to operate if tipped on its side, canister capacity will be reduced. Keep a spare 300 ml disposable canister within reach.**


Figura 8


Figura 9

### 4.3 Functioning


- On/off
- External power: Supplied from AC to DC Adapter/Charger or 12V DC Power Cord. Illuminates in GREEN when power is supplied.
- Battery charging: Illumintes in YELLOW. The light will go out when the battery is fully charged.
- Low battery. Illuminates in RED when battery reaches a discharged state.
- mmHg • Suction level setting: Scale/strength illuminates in GREEN. This scale shows the level of suction strength in mmHg.

**Power Source Options**


Figura 11

**AC OPERATION** - Plug the 90 degree power connector of AC to DC Adapter/Charger into DC power input (FIG 11) and connect the line cord. Plug the other end of AC to DC Adapter/Charger into a grounded AC supply.

**12V DC OPERATION** - Plug the small 90 degree power connector of 12V DC power cord into DC power input (FIG 11). Plug large end of cord into 12V DC power receptacle of vehicle.

**BATTERY OPERATION** - Your unit is equipped with a high capacity rechargeable battery. For initial charge on new unit, fully charge the battery for a minimum of 5 hours (please see Battery Charging).

**To operate unit from the rechargeable battery, ensure that no external power sources are plugged into the suction unit.**

**During charging or operating, the power supply may become warm to touch; this is normal.**

**If you get the Low Battery Warning symbol, immediately switch to an external power source to avoid an interrupted suction procedure.**

**If the unit does not receive external power or the battery does not get recharged immediately, the low battery indicator light will remain on and the performance of the unit will drop off rapidly and then shut down.**

#### 4.3.1 Adjust The Vacuum Level


Figura 12

1. Once power source is selected, turn the unit on by pressing the “On” button. The GREEN light, representing external power, will remain lit when external power is connected.
2. Occlude (block) the patient end of the tubing, then adjust vacuum level from 50 to 550 mmHg by turning the vacuum regulator knob clockwise to increase and counter-clockwise to decrease the vacuum (fig. 12). Release and occlude once more to confirm setting. The desired level of vacuum can be viewed on the LED display (fig. 10).

**The LEDs have two brightness levels. As the vacuum level is adjusted the LEDs will illuminate in progression. When an LED is at half brightness, it indicates that the vacuum level is halfway between the previous fully lit LED and the half brightness LED. EXAMPLE: If the 150 mmHg LED is fully illuminated and the 200 mmHg LED is at half brightness, this indicates that the suction level is 175 mm Hg. When the 200 mmHg LED illuminates at full brightness, this indicates the unit has reached 200 mmHg. Attention should be taken when setting the different vacuum levels; and it might be necessary to adjust the suction level to local protocol during use.**

3. Connect suction tip or catheter as appropriate.

**If the unit does not maintain vacuum, refer to Troubleshooting.**

4. For Jet Wire (SC75400B), suction ceases when liquid level reaches float shut-off valve located on underside of 1000 ml canister lid.
5. For Jet Compact (SC75100B), suction ceases when liquid level reaches filter located inside 300 ml canister.

**Dispose of canister and/or contents according to local protocol.**

**Further suctioning attempts with a full canister may cause damage to the vacuum pump and voids warranty. Equipment service is required if fluid content is aspirated back into the unit.**

#### 4.3.2 Battery charging

Models Jet Compact and Jet Wire are equipped with a factory-installed high capacity rechargeable battery. Located on the display panel is the low battery and charge indicator light (fig. 10)

1. Connect the unit to a power source.
2. The green external power light shall be illuminated. The yellow charge indicator will remain lit while the battery is charging.
3. Ensure that the yellow charging light is illuminated when charging begins. As the battery nears a full charge, the yellow battery charging light may flash for several minutes. This is normal. If your unit does not hold a charge, check that the yellow light turns on when external power is applied with the power button “Off”. If problems persist, contact an authorized Spencer italia Srl Service Center.

**Recharging the battery to full capacity may take up to 5 hours depending on the depth of discharge.**

If unit is not in use for extended periods, the battery should be recharged every 3-6 months. A fully charged battery will provide approximately 45-60 minutes of continuous operation at zero vacuum level (free flow). Unit can be left on charge when not in use.

**Completely discharging the battery will shorten the battery life. Do not operate the unit for more than a few minutes if the low battery indicator light is lit. Recharge the battery as soon as possible.**

#### 4.3.3 Battery replacement (par. 4.2.1)

1. Using a coin or straight-blade screwdriver rotate latch to unlocked position.
2. Remove door by pulling up on latch.
3. Remove battery from compartment and unplug connector from circuit board.
4. Install new battery by reversing the above steps.
5. Dispose of battery properly by following local protocol.

#### 4.3.4 Collection canister

1. To remove canister, push power button to turn unit off. Wait for vacuum level to drop.
2. Disconnect external power source from input receptacle on unit (if applicable).
3. Remove canister from unit or holder by disconnecting the elbow, tubing and filter as needed.

**Insert tethered plug into side port of unit.**

4. It is possible autoclave the 1000ml canister: insert the parts in autoclave and to effect a cycle of sterilization with vapour to the temperature of 120 °C (pressure relative 1 bar) having care to position turned upside - down the graduated jar (with turned fund toward the tall one). After the sterilization and the cooling to the temperature the components' environment, to verify that this last don't result damaged; disassembled therefore the container for inhaled liquids following the inverse operations to the dismantlement.
5. The 300 ml disposable collection canister is meant for single-use only and must be discarded after use..


Figura 13

**Before disposal of the 300 ml canister, attach free end of tubing to the fitting at the bottom of the canister (fig. 13). This prevents liquid from leaking out of the canister.**

#### 4.3.5 Changing filter

1. Filter can be used for up to 2 months of use, but change filter immediately if contamination or discoloration is observed.
2. Remove the bacteria filter by disconnecting it from the suction unit and lid assembly.
3. Replace it with a new Bacteria Filter and remount it to the suction unit and disposable canister lid.

**Verify clear side of filter marked <In> faces canister (fig. 14).**

**Use only the Bacteria Filter provided by Spencer Italia Srl or one of its Distributors. Substitution may lead to contamination of the unit and/or poor performance and will void warranty.**


Figura 14

### 4.4 Troubleshooting

**If problem is not resolved, contact your authorized Spencer Italia Srl Service Center:**

| PROBLEM | REMEDY |
|---|---|
| Unit does not power on. (Green external power indicator should be illuminated when power is applied.) | 1. Check power sources and connections.<br>2. Ensure wall outlet is live by plugging in a lamp.<br>3. If operating from 12V DC, ensure DC outlet is live by plugging in known working device such as a cell phone charger.<br>4. Verify that battery is properly installed, connected and fully charged before use. |
| Pump runs, but no vacuum. | 1. Check that all tubing is connected properly.<br>2. Check tubing connections for breaks, leaks, or occlusions.<br>3. Ensure that 1000 ml suction canister float shut-off is not activated or that 300 ml canister filter is not clogged.<br>4. Check for leaks or cracks in canister assembly. |
| Low vacuum. | 1. Use vacuum adjustment knob to increase vacuum level (return to local protocol level after test).<br>2. Check system for leaks. |
| Battery will not hold a charge. (Charge indicator should be illuminated if wbattery is connected during charge mode.) | 1. Verify that charge light turns on.<br>2. Check electrical connections during charging.<br>3. Ensure wall outlet is live by plugging in a lamp. |
| Battery seems insufficient, does not hold charge. | 1. Perform the following test to determine if battery replacement is necessary:<br>a. Charge battery as directed.<br>b. Disconnect charging accessory and operate the aspirator at free flow (no suction load and tubing unobstructed) for 20 minutes.<br>2. If aspirator stops before completing the 20 minutes, contact an authorized Spencer italia Srl Service Center for advice regarding battery replacement. |

**Electric shock hazard. Do not attempt to open or remove cabinet, there are no user-serviceable internal components. If service is required, return the suction unit to an authorized Spencer Italia Srl Service Center. Opening or tampering with the unit will void the warranty**

## 5. MAINTENANCE AND CLEANING

### 5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals.

**The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.**

**Cleaning suction unit**

1. With the power "Off," disconnect the unit from all external power sources.
2. Wipe the outside housing with a clean damp cloth and detergent.

**Do not submerge suction unit in water as this will result in damage to vacuum pump.**

3. If disinfection is desired, follow the disinfectant manufacturer's recommended instructions and dilution rates carefully.

**Cleaning tubing**

1. Disconnect tubing and discard; both patient tubing and connection tubing are considered single-patient use only.

### 5.2 Maintenance

#### 5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) 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.

**During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.**

Checks to be carried out before and after each use, and at least every 3 months, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure to follow cleaning instructions may cause the risk of cross contamination)

- Integrity of components

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage. Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. The Manufacturer and Spencer Italia S.r.l. decline any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subjected to routine maintenance warranty and will void the compliance to the Medical Device Directive 93/42/CEE.
The person responsible for routine maintenance can identify damaged/worn parts, but the replacement or restoration of them can only be done by the manufacturer or or by an authorized service center.
Use only accessories/original spare parts approved by the Manufacturer, otherwise we will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorized Service centers. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

### 5.2.2 Special servicing

**Only the Manufacturer or centers with written authorization are authorized to complete any special servicing operations.**
For any operations that are not carried out directly by the Manufacturer but by an authorized centre, we have to underline that a report regarding all operations carried out must be requested. This will permit the Manufacturer, Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.
The Manufacturer and Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired by the Manufacturer or by one of the Manufacturer's Authorized Service centers, making void the guarantee and the conformity to the Medical Devices Directive 93/42/CEE.

## 6. ACCESSORIES AND SPARE PARTS

### 6.1 Accessories

| | |
|---|---|
| SC73017E | Power supply 220 V (Schuko) |
| SC75011E | Transport Bag for Jet Compact |

### 6.2 Spare parts

| | |
|---|---|
| SC75013E | Battery door |
| SC75007B | High capacity rechargeable battery 12V CC Ni-MH |
| SC75014E | Power supply cable 12V lighter |
| SC75001E | Disposable collection vase 300 ml with patient tube |
| SC73013E | Antibacterial filter |
| SC73016E | Patient tube 1,8 m |
| SC70079C | 90° elbow for vase connection |
| SC70085A | Reusable collection vase 1000 ml |
| SC70078E | Tube for connection of 1000 ml vase |
| SC70077E | Kit filter/tube/connection |
| SC75005B | Elbow for unit connection |

**Manufacturer:**

DeVilbiss Healthcare LLC

100 DeVilbiss Drive

Somerset, PA 15501-2125 USA

**European Representative:**

DeVilbiss Healthcare GmbH

Kamenzerstraße 3

68309 Mannheim

Germany

## ATTACHMENT A – TRAINING REGISTER

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

Keep this document at least 10 years from the end of life of the device.

| Operator's name | Training date | | Training method (user's manual, during service, former class, etc.) | Trainer |
|---|---|---|---|---|
| | Basic training | Advanced training | | |
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**ATTACHMENT B – MAINTENANCE REGISTER**

Keep this document at least 10 years from the end of life of the device.

Perform the required maintenance for the entire life of the device, as indicated by the Manufacturer in the User's Manual.

| | |
|---|---|
| **Code and description of the device** | |
| **Purchase date** | |
| **Lot (LOT) or serial number (SN)** | |
| **Bought by** | |

| SERVICE DATE | KIND OF SERVICE (Maintenance/ check/ extension of life span) | TYPE OF REPAIR MADE ON THE DEVICE | RESULT: PASS/FAIL | PERSON IN CHARGE OF SERVICE (Operator/ Authorized center/ Manufacturer) |
|---|---|---|---|---|
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**Warning**

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.