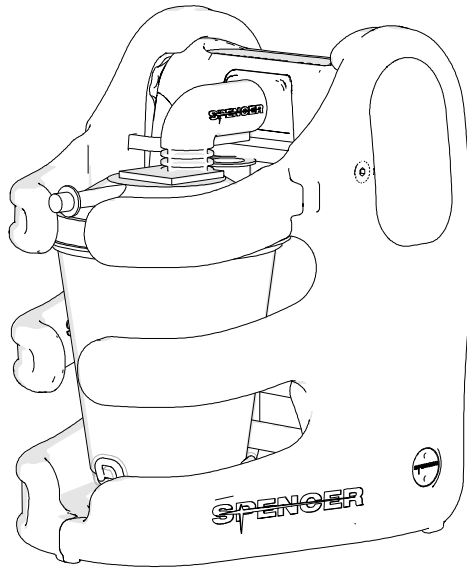
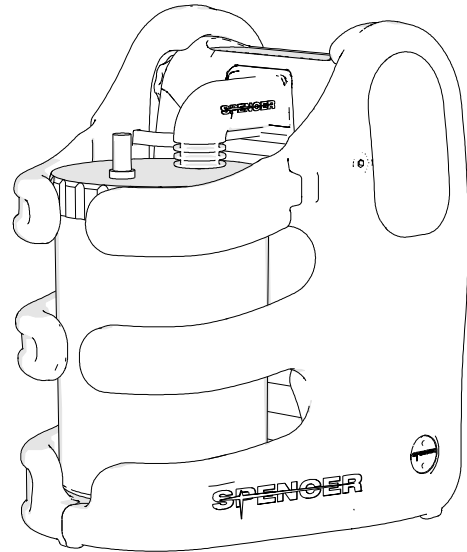
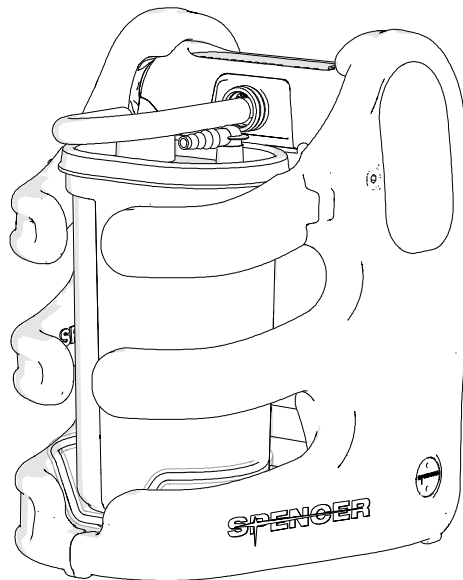




800 D



1000 R



1000 B

Use and maintenance manual HOME JET and AMBU JET EN Portable suction unit

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SPENCER ITALIA SRL – Via Provinciale n° 12
43038 Sala Baganza (PR) – Italy

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 and/or specific warning
	Consult instruction for use
	Serial Number
	Catalogue number
	The product is compliant with the specifications of the Directive 93/42/CEE
	Type BF applied part , compliant IEC 60601-1
	Alternating current
	Direct current
	Parts of this product are designed for single patient use only
	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. – Via Provinciale, 12 - 43038 Sala Baganza (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

Follow the current regulations.



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 equipment's 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 organized 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 organized 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 unauthorized 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.
- While using the device must be guaranteed the assistance of qualified personnel.
- 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 Country, 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.
- 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 non-flammable 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.
- 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 anaesthetic 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.
- 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 canister within reach in case the canister in use is full or the filter becomes wet.
- The suction units are certified to EN 1789 when used with fixing systems Spencer inside ambulances, so it is prohibited to use still not approved by the manufacturer. Fixing systems not approved can alter the structural and functional characteristics of the device.
- The filter group must be entirely replaced. It's not enough to replace only the internal filtration element.

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.

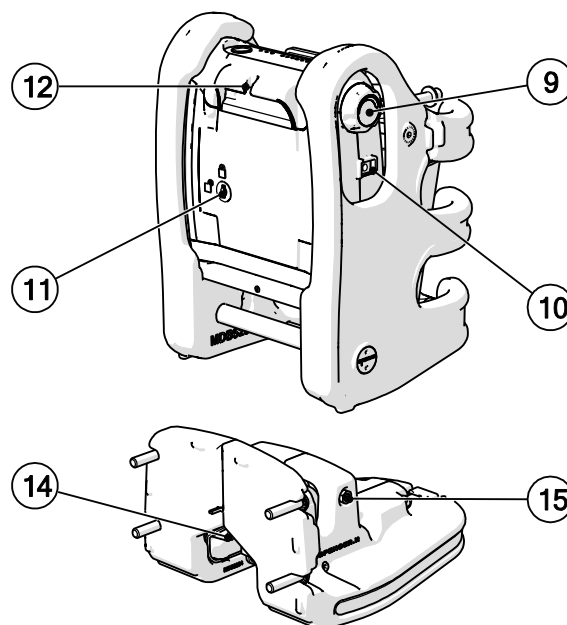
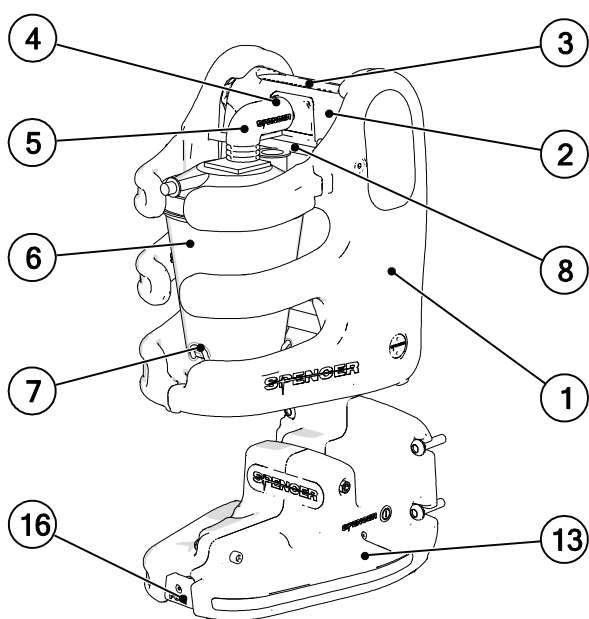
3. DESCRIPTION OF PRODUCT

3.1. Intended use

The HOME JET and AMBU JET is a portable, electrically powered, medical suction equipment intended for field and transport use. It is intended for intermittent operation to remove secretions, blood or vomit from a patient's airway to allow ventilation. Higher vacuum levels are generally selected for oropharyngeal suctioning, and lower vacuum levels are usually selected for tracheal suctioning and the suctioning of children and infants.

3.2 Main components

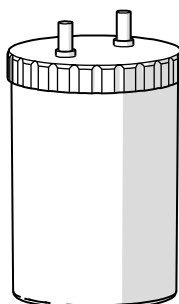
n°	Description component	n°	Description component
1	Shell protection	11	Battery door
2	Suction unit	12	Unit Carry Handle/Catheter Holder
3	Display Panel (top of unit)	13	Shell of the fixing (where present)
4	Connector	14	Fusible (where present)
5	Disposable Filter group	15	Contact Points automatic recharge (where present)
6	Canister	16	Release button fixing (where present)
7	Backing support vessel (where present)	17	1,8 m Patient Tubing
8	Fixing Traverse	18	High Capacity Rechargeable Battery (not shown)
9	Vacuum Regulator Knob	19	Shoulder strap and handle auxiliary transport
10	DC Power Input	20	Hooks for fixing to the floor
		21	Power plug for 12V vehicle cigarette lighter



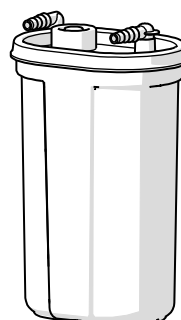
CANISTER TYPE



800 ml
single use

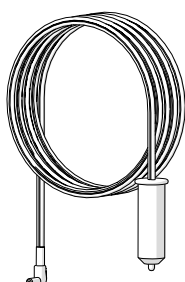


1000 ml
reusable

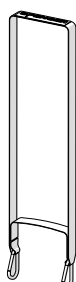


1000 ml
Serres with bag

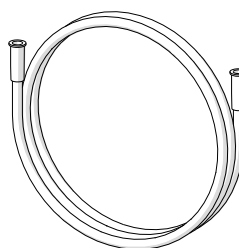
SEPARATE COMPONENT



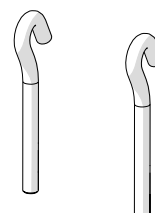
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17



20

3.3 Models

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

Code	Description	Characteristics
SC75200D	HOME JET 800D	Canister single use 800ml
SC75210D	HOME JET 1000B	Canister with bag Serres single use 1000ml
SC75300D	HOME JET 1000R	Canister reusable 1000ml
SC75500C	AMBU JET P 800D 20G	Canister single use 800ml with fixing 20G and automatic recharge
SC75510D	AMBU JET P 1000B 20G	Canister with bag Serres single use 1000ml with fixing 20G and automatic recharge
SC75550C	AMBU JET P 800D 10G	Canister single use 800ml with fixing 10G and automatic recharge
SC75560D	AMBU JET P 1000B 10G	Canister with bag Serres single use 1000ml with fixing 10G and automatic recharge
SC75600C	AMBU JET P 1000R 20G	Canister reusable 1000ml with fixing 20G and automatic recharge
SC75650C	AMBU JET P 1000R 10G	Canister reusable 1000ml with fixing 10G and automatic recharge
SC75700C	AMBU JET 800D 20G	Canister single use 800ml with fixing 20G
SC75710D	AMBU JET 1000B 20G	Canister with bag Serres single use 1000ml with fixing 20G
SC75750C	AMBU JET 800D 10G	Canister single use 800ml with fixing 10G
SC75760D	AMBU JET 1000B 10G	Canister with bag Serres single use 1000ml with fixing 10G
SC75800C	AMBU JET 1000R 20G	Canister reusable 1000ml with fixing 20G
SC75850C	AMBU JET 1000R 10G	Canister reusable 1000ml with fixing 10G

3.4 Technical data

Characteristics	
Dimension	200 x 225 x h285 mm (7,9 x 8,8 x 11,2 inch) / 200 x 250 x h320 cm (7,9 x 9,8 x 12,6 inch .) with fixing
Weight	2,4±0,1 kg (5,29 lbs.)/ 3,1±0,1 kg (6,83 lbs.) with fixing
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 mmHg (±27,5 mmHg) / from 67 to 733 mBar (± 37 mBar)
Air flow	32 lpm
Capacity of canister	1000 ml reusable or with bags single use / 800 ml single use
Operating mode	30 min. on , 30 min. off
Decibel noise level	70 dB
Degree of protection against ingress of liquids	IP12 and standard power supply
Protection from electric shock	Class I e alimentation internal
Protection level from electric shock	Type BF Applied Parts
ISO 10079-1:1999 classification	High flow/High vacuum
Directive 93/42/CE classification	Ila

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 electrometrical devices
UNI EN ISO 14971	Medical devices -- Application of risk management to medical devices
RTCA/DO-160E, Section 21 Category M (only for battery powered) Commercial airlines, airline equipment *	Environmental Conditions and Test Procedures for Airborne Equipment - Section 21: Emission of Radio Frequency Energy
IEC 68-2-27 (= CEI EN 60068-2-27)	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
IEC 68-2-6 (= CEI EN 60068-2-6)	Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal) and guidance
IEC 68-2-64 (=CEI EN 60068-2-64)	Environmental testing - Part 2: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance
UNI EN 1789	Medical Vehicle and their equipment

*Standard not applicable to models SC75500C, SC75510C, SC75550C, SC75560C, SC75600C, SC75650C

3.6 Environmental conditions

Operating Temperature Range	from 0°C to 40°C
Operating Relative Humidity	from 0 to 95%
Operating Atmospheric Pressure	from 70 kPa to 106 kPa
Storage & Transport Temperature Range	from -40°C 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 in accordance to the specified in the condition in section 3.6. 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 Connection battery



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 (n°11 paragraph 3.2) by pulling up on latch (fig. 2).
3. Remove battery (n°18 paragraph 3.2) 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 Alimentation

ALIMENTATION CA 100-240V (47/63Hz) – Plug the 90 degree power connector of AC to DC Adapter/Charger (accessories code SC73017E) into DC power input (n°10 paragraph 3.2) and connect the line cord. Plug the other end of AC to DC Adapter/Charger into a grounded AC supply.

ALIMENTATION 12V CC – Plug the small 90 degree power connector of 12V DC power cord into DC power input (n°10 paragraph 3.2). Plug large end of cord into 12V DC power receptacle of vehicle.

BATTERY ALIMENTATION – 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).

AUTOMATIC RECHARGE ALIMENTATION 12V CC ON FIXING SYSTEM – Insert the suction unit on fixing with automatic refill and check that the LED corresponding to the charging lights.

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.

Per utilizzare il dispositivo con alimentazione a batteria, verificare che non sia collegato a sorgenti di alimentazione esterne.

4.2.3 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 (watch paragraph 4.3.1. Display interface).

1. Connect the unit to either an AC or DC 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 S.r.l. 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.

The internal battery warranty is limited to 90 days

4.2.4 Fixing Shoulder strap and handle auxiliary transport

Attach the shoulder strap (n°19 paragraph 3.2) as shown in figure 4 through the carabineers to the fixing traverse (n°8 in paragraph 3.2) and then make the required adjustment

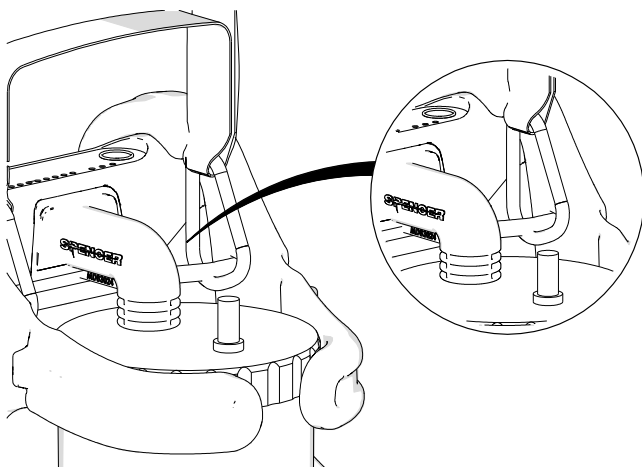


Fig. 4

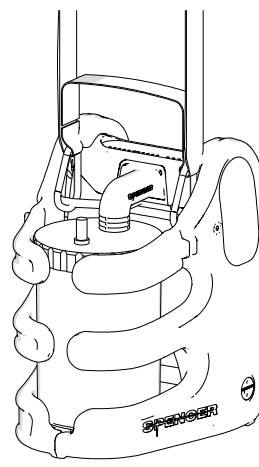


Fig. 5

4.2.5 Canister connection

4.2.5.1 Connection canister 800ml single use

For the assembly operations of the canister refer to the instructions provided within the canister.

1. Connect to the canister the filter group (n°5 in paragraph 3.2), put the canister in his support deforming slightly the body at the top (fig. 6); verify that the backing support canister (n°7 in paragraph 3.2) is lowered and properly fastened to the body of the suction unit.
2. Connect the assembly filter group/canister to the suction unit by turning the canister and the assembly filter to facilitate insertion (fig.7 e 8).
3. Connect the patient tubing (n°17 paragraph 3.2) to the plug of the canister in the door marked with the words "Patient". Verify that all connections are tight to prevent leakage of liquids and depression (Fig. 8).
4. Connect the patient tubing to the aspiration catheter compatible (not supplied) according to the needs of use.

For each use it is necessary to replace the filter group. Use only filters supplied by Spencer

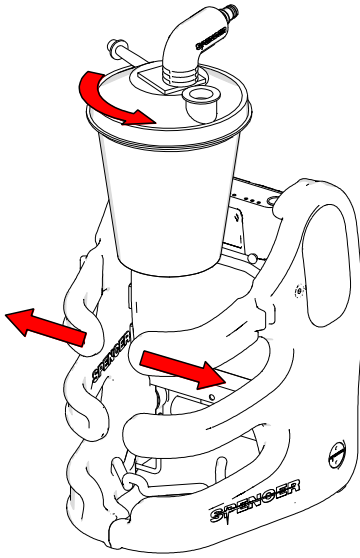


Fig. 6

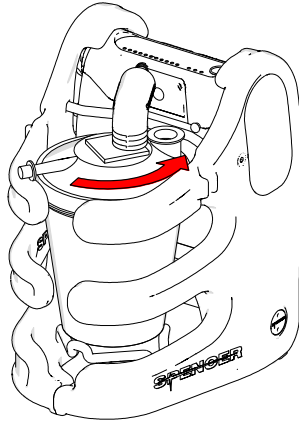


Fig. 7

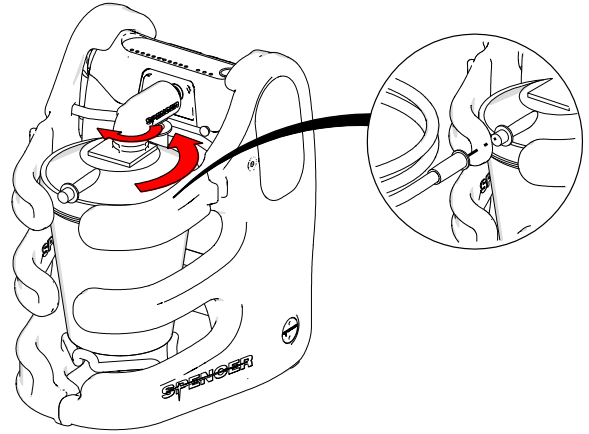


Fig. 8

4.2.5.2 Connection canister 1000ml reusable

1. Connect to the canister the filter group (n°5 in paragraph 3.2), put the canister in his support (fig.9).
2. Connect the assembly filter group/canister to the suction unit by turning the canister and the assembly filter to facilitate insertion (fig.10 e 11).
3. Connect the patient tubing (n°17 paragraph 3.2) to the plug of the canister in the door marked with the words "Patient". Verify that all connections are tight to prevent leakage of liquids and depression (fig. 11).
4. Connect the patient tubing to the aspiration catheter compatible (not supplied) according to the needs of use.

For each use it is necessary to replace the filter group. Use only filters supplied by Spencer.

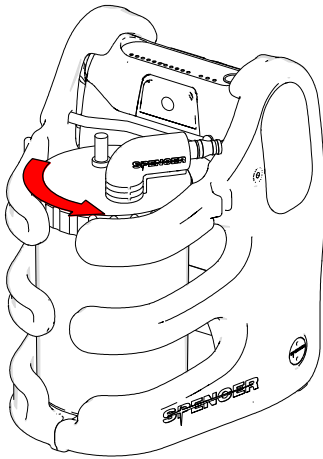


Fig. 9

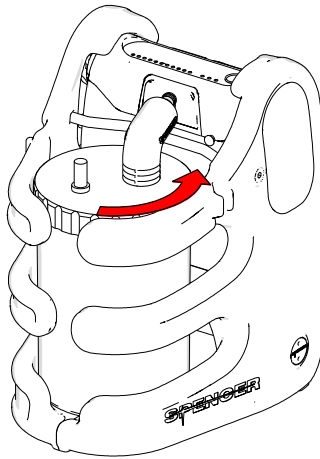


Fig. 10

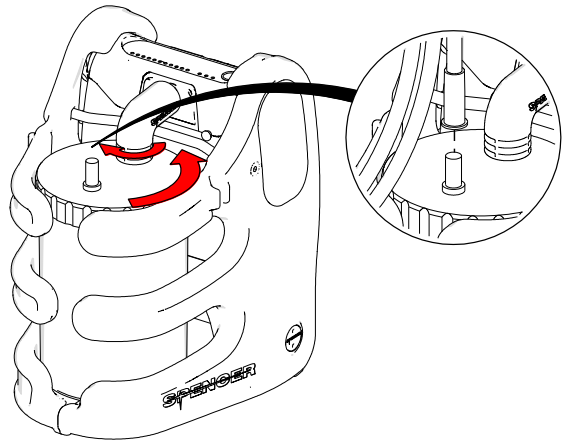


Fig. 11

4.2.5.3 Connection canister 1000ml Serres with bag

For the assembly operations and replacement bag of the canister Serres refer to the instructions provided within the canister. Put the canister in its support (fig. 12); verify that the backing support canister (n°7 in paragraph 3.2) is lowered and properly fastened to the body of the suction unit

1. Connect to the suction unit the connector (n°4 paragraph 3.2).
2. Connect the tube between canister and connector (fig.14).
5. Connect the patient tubing (n°17 paragraph 3.2) to the plug of the canister in the door marked with the words "Patient". Verify that all connections are tight to prevent leakage of liquids and depression.
6. Connect the patient tubing to the aspiration catheter compatible (not supplied) according to the needs of use.

For each use it is necessary to replace the filter group. Use only filters supplied by Spencer.



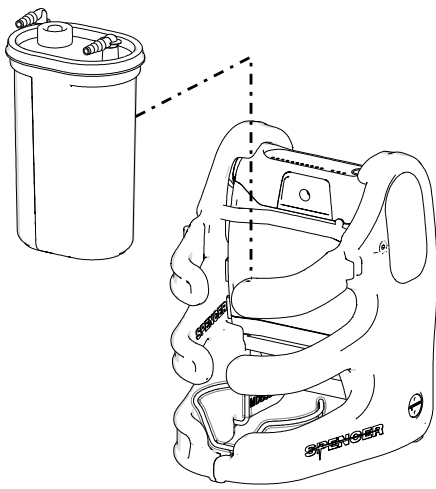


Fig. 12

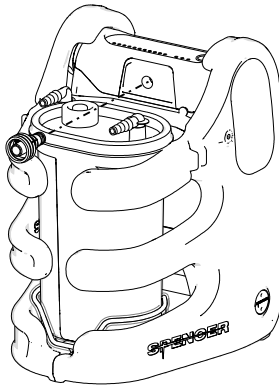


Fig. 13

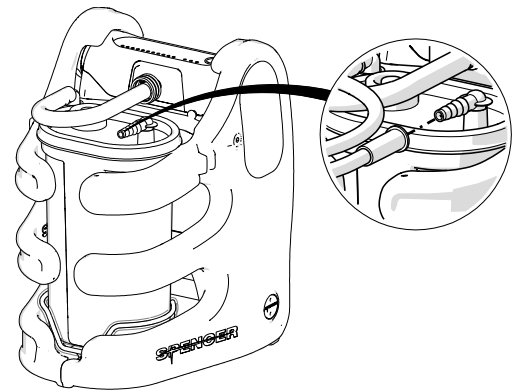


Fig. 14

4.2.5.4 Filter assembly sequence

This operation is necessary only if the components are no longer assembled after transport or have been separated during installation of the filter group.



Keep the orientation of the inner filter when reassembling.

4.2.6 Fixing Installation (where present) ONLY SPECIALISED MEDICAL VEHICLE BUILDER IS AUTHORISED TO ATTACH FIXING UNIT

• 10G Fixing

Check that the position where you want to fix the product the operation of hooking and unhooking the suction device can be done correctly and safely.

1. Choose a suitable location within the medical vehicle with enough free space for the installation of the wall bracket. The surface on which you install the fastener must be flat and perpendicular to the floor of the vehicle.
2. Choose metallic fasteners that will securely hold the wall bracket to the chosen mounting surface. The strength and size of the screws must be sufficient to hold the bracket to the wall under the force of over 10G. We recommend the use of 4 x M8 TBEI ISO 7380 screws.
3. Place the hook into the chosen location and mark the points in which the screws will be fixed. If present mark also the position of hole for the power cable of the automatic recharger.
4. Drill the holes where the screws will be inserted and the hole for the cable.
5. Connect the 12V power to the vehicle, the red wire is the positive polarity and black negative polarity. Do not bend the cable over sharp edges. We recommend placing a sheath / protection on the cable to protect it. The cable is 1m long.
6. Fasten the screws to the vehicle structure so that the attachment can withstand the 10G force and vibration of the vehicle in use. Insert the screws (not supplied) toothed washers (supplied) and anti-vibration bushes (supplied) only in the two upper to ensure a larger surface and a appropriate fixing.
7. Before use, check that you have correctly installed the fixing by doing a test run with the suction device.

The automatic recharger attachment is equipped with a F 5A fuse (No. 14 paragraph 3.2) to prevent damage to the electrical system of the suction device. The attachment is equipped with automatic adjustment of contact points for recharger of suction device. When supplied the attachment has the correct setting for functioning. If adjustment is necessary contact the Spencer Srl service center.

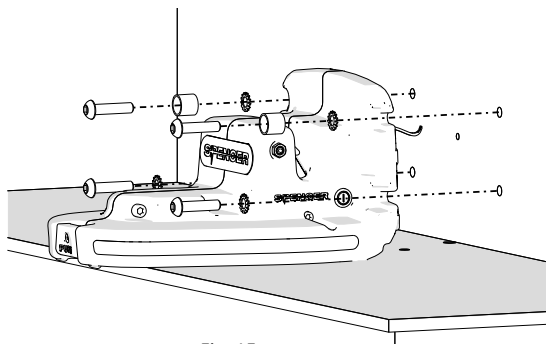


Fig. 15

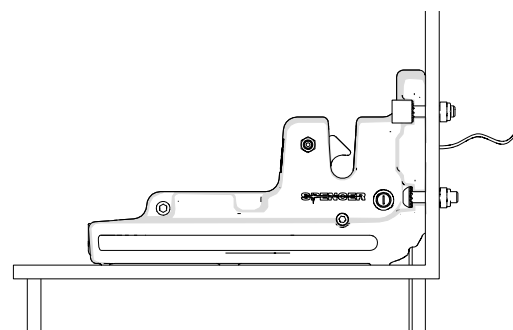


Fig. 16

• 20G fixing

Check that the position where you want to fix the product the operation of hooking and unhooking the suction device can be done correctly and safely.

1. Choose a suitable location within the medical vehicle with enough free space for the installation of the wall bracket. The surface on which you install the fastener must be flat and perpendicular to the floor of the vehicle.
2. Choose metallic fasteners that will securely hold the wall bracket to the chosen mounting surface. The strength and size of the screws must be sufficient to hold the bracket to the wall under the force of over 20G. We recommend the use of 4 x M8 TBEI ISO 7380 screws. In the 20 G version 2 fixing hooks (n°20 paragraph 3.2) have to be applied to the base surface along with the large width washers (supplied) which will then be screwed on using a self locking M8 nut (not supplied).
3. Place the hook in the chosen location and mark the points in which the screws will be fixed. If present, mark also the position of hole for the power cable of the automatic recharger. Then mark the holes for to fix the hooks. See picture 17 for instructions on how to fix the fixing hooks.
4. Drill the holes where the screws will be inserted and the hole for the cable.

5. Connect the 12V power to the vehicle, the red wire is the positive polarity and black negative polarity. Do not bend the cable over sharp edges. We recommend placing a sheath / protection on the cable to protect it. The cable is 1m long.
6. Fasten the screws to the vehicle structure so that the attachment can withstand the 20G force and vibration of the vehicle in use. Insert the screws (not supplied) toothed washers (supplied) and anti-vibration bushes (supplied) only in the two upper to ensure a larger surface and an appropriate fixing. To fix the hooks, position the large width washers under the surface on which the fixing is applied so as to increase the contact surface. **Do not over tighten the hooks as it could deform the fixing mechanism and make it not compliant for use.**
7. Before use, check that you have correctly installed the fixing by doing a test run with the suction device.

The automatic recharger attachment is equipped with a F 5A fuse (No. 14 paragraph 3.2) to prevent damage to the electrical system of the suction device. The attachment is equipped with automatic adjustment of contact points for recharger of suction device. When supplied the attachment has the correct setting for functioning. If adjustment is necessary contact the Spencer Srl service center.

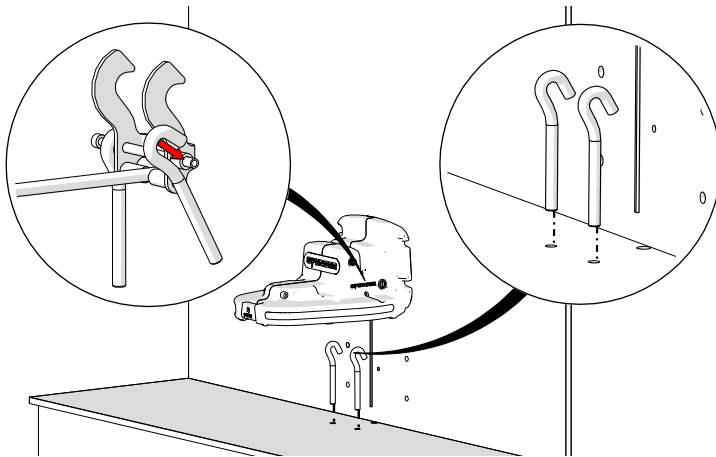


Fig. 17

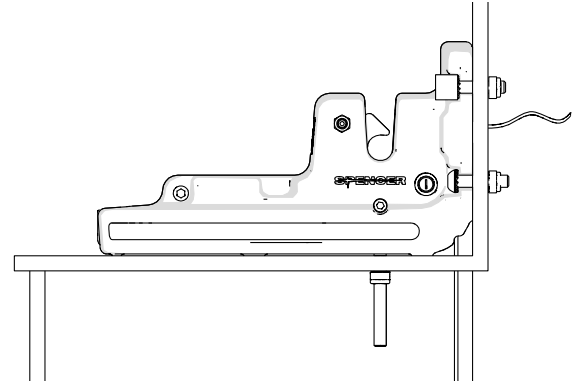


Fig. 18

4.3. Functioning

4.3.1. Interface Display



On/off, command on and off suction



External power: Supplied from AC to DC Adapter/Charger or 12V DC Power Cord. Illuminates in GREEN when power is supplied.



Battery charging: Illuminates in YELLOW. The light will go out when the battery is fully charged.



Low battery. Illuminates in RED when battery reaches a discharged state.



Fig. 19

mmHg Suction level setting: Scale/strength illuminates in GREEN. This scale shows the level of suction strength in mmHg.

4.3.2. Adjust The Vacuum Level

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 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. 20). Release and occlude once more to confirm setting. The desired level of vacuum can be viewed on the LED display (fig. 10).
3. 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 mmHg. 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. Suction ceases when liquid level reaches float shut-off valve located on underside of canister lid., or push "On/Off".

Keep the container filled with aspiration may cause damage to the vacuum pump and void the warranty. If you continue to aspirate fluid into the content it is necessary to subject the equipment to maintenance.

4.3.3. Fixing patient tubing

On both sides of the shell protection there is a quick coupling for the patient tube, in case it is necessary to temporarily support the tube and cannula (fig.21).

4.3.4. Battery replacement

1. Using a coin or straight-blade screwdriver rotate latch to unlocked position (fig. 1).
2. Remove door (n°11 paragraph 3.2) by pulling up on latch (fig. 2).
3. Remove battery (n°18 paragraph 3.2) from compartment and detach plug connector from the 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).

Accordance with local regulations for disposal of batteries, see section 1.5 "Disposal"

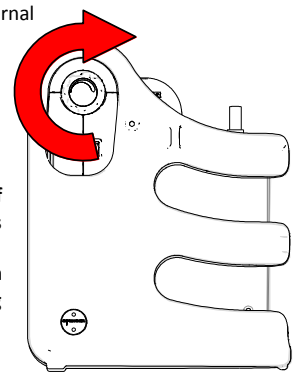


Fig. 20

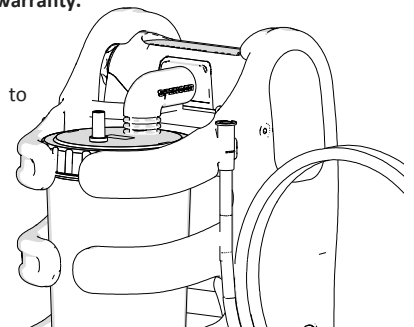


Fig. 21

4.3.5. Changing filter

1. Remove the bacteria filter by disconnecting it from the suction unit and lid assembly.
2. Replace it with a new filter and remount it to the suction unit

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

4.3.6. Replacing the canister

Before removing the container do the following:

1. Ensure that the device is turned off.
2. Ensure that the container is not still subject depression and if so wait until it falls.
3. Disconnect the filter / fittings / tubes from the suction unit.

4.3.6.1. 800 ml disposable canister

Seal the suction access and patient access with the connected plugs. Remove the container from the suction device and take it to the disposal area. Do not lift the container by the lid, as the weight of the contents may cause separation from the container.



Canister exclusively for single use. Do not attempt to clean, sterilise or to re-use. Re-use could be the cause of implosion, fluid leakage and exposure to blood borne pathogens. The contents of the vase are to be considered potentially dangerous and the correct individual protection devices should be worn and the appropriate manipulation procedures followed.

4.3.6.2. 1000 ml reusable canister

Remove the pot from the extractor being careful not to spill the contents.

Washing and / or cleaning of the autoclavable canister must be carried out according to the following scheme:

1. Wear gloves, apron, goggles and face mask so as to avoid any contact with any contaminants.
2. Drain and dispose of the contents of the bottle as required by local laws and regulations.
3. Disconnect all parts of the lid (overflow, seal).
4. Disassemble the bottle and place under cold running water and rinse well. Following this immerse the hot water (temperature not exceeding 60 ° C). Wash thoroughly and if necessary, use a non-abrasive brush to remove any deposits. Rinse with warm running water and dry all parts with a soft, non-abrasive cloth.

It is possible to autoclave the accessories and lid: put the parts in an autoclave and proceed with a sterilization steam cycle at a temperature of 121 ° C (relative pressure 1 bar - 15 min.) Take care to position the graduated canister upside down (with the bottom facing up). The mechanical strength of the container is guaranteed for up to 30 cycles of cleaning and sterilization under the conditions specified (EN ISO 10079-1). Beyond this limit physical - mechanical characteristics of plastic may occur therefore replacement is recommended.

Once after sterilization the components have cooled to room temperature, check that the parts have no damage; then reassemble the vase following these steps:

1. Take the lid and place the floating support in the slot (under the VACUUM connector)
2. Insert cage float and float with the seal facing towards the opening of the cage
3. Place the gasket into the seat cover
4. Once reassembled, always make sure the lid is properly closed to prevent vacuum leaks and spillage of liquids.

4.3.6.3. 1000 ml Serres canister with bag

Seal the access of suction and patient access with the connected plugs. Remove the container from the extractor and take it to the disposal area. Remove the disposable bag and dispose of it in accordance with the procedures adopted by the local health care system.

If it is necessary to clean the vase and the angled connector they can be washed at 85 ° C or autoclaved at 121 ° C. Before washing or sterilization detach the angled connector.



Liner bag for single use only. Do not try to clean, or sterilize or reuse it. Re-use could cause implosion, fluid leakage and exposure to blood borne pathogens. The contents of the liner bag are to be considered potentially dangerous and the correct individual protection devices should be worn and the appropriate manipulation procedures followed.

Always use the original Serres liner bags (see 6.2 "Spare Parts"), as other brands of liner could compromise the use.

4.4. Troubleshooting

Before returning the unit to a service center Spencer Italy Srl, follow the protocol for the identification of faults below:

PROBLEM	REMEDY
Unit does not power on. (Green external power indicator should be illuminated when power is applied.)	1. Check power sources and connections. 2. Ensure wall outlet is live by plugging in a lamp. 3. If operating from 12V DC, ensure DC outlet is live by plugging in known working device such as a cell phone charger. 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. 2. Check tubing connections for breaks, leaks, or occlusions. 3. Ensure that 1000 ml suction canister float shut-off is not activated or that 300 ml canister filter is not clogged. 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). 2. Check system for leaks.
Battery will not hold a charge. (Charge indicator should be illuminated if w battery is connected during charge mode.)	1. Verify that charge light turns on. 2. Check electrical connections during charging. 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: a. Charge battery as directed. b. Disconnect charging accessory and operate the aspirator at free flow (no suction load and tubing unobstructed) for 20 minutes. 2. If aspirator stops before completing the 20 minutes, contact an authorized Spencer Italia S.r.l. Service Center for advice regarding battery replacement.
The charging system is not working automatically	1. Fuse to be replaced (contact service center or manufacturer) 2. Damage contacts (contact service center or manufacturer)



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 S.r.l Service Center. Opening or tampering with the unit will void the warranty

4.5. Return mode for repair

In accordance with new European regulations, Spencer Italia S.r.l. lists some key points to preserve the hygiene of the equipment and operators who use them. Spencer Italia S.r.l. trusts in compliance with these standards in order to ensure hygiene and health to all the people who work to achieve quality and well-being.

Every device that will be returned to Spencer Italia S.r.l. will undergo health checks before the repair.

If Spencer Italia S.r.l. judges the instrument not suitable for repair because of visible signs of external and/or internal contamination, will send the device to the customer with specification NOT REPAIRED, attaching a letter of explanation of the defects. Spencer Italia S.r.l. will decide if contamination is due to a malfunction or misuse.

If the contamination is due to a malfunction, Spencer Italia S.r.l. will replace the product only in presence of a SALE RECEIPT and STAMPED GUARANTEE.

Spencer Italia S.r.l. does not respond for the accessories that show signs of contamination, then will replace the same charging material costs to the customer. For the above, the device MUST be carefully disinfect on the outer casing with a cloth moistened with denatured alcohol or solutions containing hypochlorite and accessories immersing them in the same disinfectant. Place it in a bag with specified equipment and accessories disinfected. Request to specify the defect in order to carry out the repair in the shortest possible time. It therefore requires to carefully read the instructions to avoid compromising the device with inappropriate use. It requires you to specify the kind of fault to give way to the technical Spencer Italy Srl to judge whether the fault falls into the category of 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 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

SC75012E	Lateral Bag Jet
SC73017E	AC Adapter 220V
SC75024	Power supply cable 12V lighter reduced pitch
DG00150A	Yankauer fixed cannula
DG00151A	Yankauer fixed cannula with control
DG00212C	DGX 50 CH/FG 12 aspiration catheter
DG00214C	DGX 50 CH/FG 14 aspiration catheter
DG00216C	DGX 50 CH/FG 16 aspiration catheter
DG00218C	DGX 50 CH/FG 18 aspiration catheter

6.2 Spare parts

6.2.1 Spare parts 800ml single use

RISC004B	Spare battery for JET
SC75013E	Battery door
SC75014E	Power supply cable 12V lighter
SC73039E	Canister 800 ml single use complete (pack to 10 pz.)
RISC005E	Disposable filter group AmbuJet – HomeJet
SC73016E	Patient tube 1,8 m
SC75009D	Shoulder strap and handle auxiliary
SC75010E	Spare fusible for fixing device with automatic recharge (only for the version with fixing device with recharge integrated)

6.2.2 Spare parts 1000ml reusable

RISC004B	Spare battery for JET
SC75013E	Battery door
SC75014E	Power supply cable 12V lighter
SC70085A	Canister 1000 ml reusable
RISC005E	Disposable filter group AmbuJet – HomeJet
SC73016E	Patient tube 1,8 m
SC75009D	Shoulder strap and handle auxiliary
SC75010E	Spare fusible for fixing device with automatic recharge (only for the version with fixing device with recharge integrated)

6.2.3 Spare parts 1000ml Serres with bags

RISC004B	Spare battery for JET
SC75013E	Battery door
SC75014E	Power supply cable 12V lighter
SC75017D	Canister Serres 1000 ml without bag
SC75018D	Bags Serres da 1000 ml (36 pz.)
RISC006C	Tube w/connector for Serres canisters Home/AmbuJet
OX10105A	Silicone tube Ø 8x14 mm (sale to mt)
SC73016E	Patient tube 1,8 m
SC75009D	Shoulder strap and handle auxiliary
SC75010E	Spare fusible for fixing device with automatic recharge (only for the version with fixing device with recharge integrated)



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.

[illegible]



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

[illegible]

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Quality System EN ISO 9001 – EN ISO 13485