SPENCER®

User's Manual

Blanco
Suction device

CE 0123 This appliance conforms with the Directive 93/42/CEE "Medical Devices"

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

INDEX

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Thank you for choosing a Spencer product

1. GENERAL INFORMATION

1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 Conservation of the instruction manual

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

1.3 Symbols used

Symbol	Meaning
	General or specific warning
	See instructions for use
SN	Serial number
REF	Product code
CE 0123	The product is compliant with the specifications of the Directive 93/42/CEE
	Instrument isolation class II (only when connected with cable car cigarette lighter, for models where it is expected)
	Type B instrument
	Applied Part type BF
~	Alternating current (where applicable)
	Direct current (where applicable)
	Fuse (where applicable)
Hz	Frequency (where applicable)
	Store in a cool, dry place
	Storage temperature
	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"
I	ON
O	OFF
	Pb Battery 12 V  (where applicable)
	Phthalates DEHP (aspiration cannula)

IP21

Degree of protection an electrical device provides in the case of accidental or intentional contact with the human body or with objects, and protection in the case of contact with water.	
1st DIGIT PENETRATION OF SOLIDS	**2nd DIGIT PENETRATION OF LIQUIDS**
Protected against solids having a dimension greater than Ø 12mm	Protected against the vertical flow of drops of water
For applicability see Technical data of each device	

1.4 Servicing request

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, please contact the Spencer Customer Care Service 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 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

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, the CE mark, the serial number (SN) or lot number (LOT). It must never be removed or covered.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- The product should be operated only by personnel trained in the use of this device.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the manufacturer in this user's manual.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- The best instructions are the continuous use under the supervision of trained and competent personnel.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Use of the device in anyway other than described in this manual is forbidden.
- Handle with care.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they

are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.

2.2 Specific warnings

- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the competent authorities and/or manufacturer if requested.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- Before connecting the appliance, always ensure that the electric data indicated on the data label and the type of plug used, correspond to those of the power network to which you want to connect it.
- If the plug supplied with the unit is incompatible with the electrical outlet, contact a qualified technician to replace the plug with a suitable type. In general, it is unwise to use adapters, multiple sockets and/or extensions. Whenever their use was indispensable, you must use accessories in compliance with safety regulations, although care should be taken not to exceed the maximum power incurred, which are indicated on the adapters and extensions.
- The device can't be used for intercostals drain.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport device in its original packaging.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Never dismantle the appliance. For any kind of intervention, contact Spencer's technical service. Any intervention, even minimum, on the device voids the warranty, and in any case does not guarantee the fulfillment of the technical requirements and safety requirements of the Directive MDD 93/42/EEC (and subsequent amendments) and related standards.
- Use only original accessories.
- The device can be used only with the bacteriological filter.
- Place instrument on stable and flat surfaces and always check to avoid the blockage of the air inlets.
- Do not use in presence of air inflammable anaesthetic, oxygen or nitrus oxide
- Do not touch the instrument with wet hands, and to avoid contact with liquids.
- Keep off the reach of children or not capable people without supervision.
- Do not leave the device connected to the power outlet when not in use.
- Do not pull cable to remove plug from the socket; to disconnect hold plug with fingers.
- Use and keep the instrument in a safe environment, protected from bad weather condition and keep off excessive heating.
- Never immerse the appliance in water.
- This appliance must be used exclusively for which it was designed and as described in this manual. Any use other than that which the device is intended is to be considered improper and therefore dangerous, the manufacturer cannot be held responsible for damage caused by improper, incorrect and/or unreasonable use.
- The Manufacturer, the emergency vehicle builder, the installer or importer are consider responsible for safety, performance and reliability only if the electrical system to which the device is connected is built according to DL46/90.
- The device requires special precautions regarding EMC and needs to be installed and used in accordance to the information provided by the manufacturer.
- No electrical and/or mechanical part contained in the suction device is designed to be repaired by the customer and/or user. Do not open the suction device, do not touch the electrical and/or mechanical properties. Always contact Spencer Italia S.r.l. technical service.
- The use of the device in environmental conditions other than those indicated in this manual, may seriously jeopardize its safety and the technical parameters.
- The lead battery contained within the medical device should not be treated as household waste. Dispose of this component at a designated collection point for recycling.
- The medical device is supplied without a specific aspiration cannula. In the case in which the suction device should to be used with a specific aspiration cannula, the end user will cure the verification of compliance with the standard EN 10079-1.
- Any suction tubes that enter the human body, separately purchased from the appliance, must comply with ISO 10993-1 norm about the biocompatibility of the materials.

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 PRODUCT DESCRIPTION

3.1 Intended use

Blanco is a suction device particularly suitable for hospital use, for patients with tracheotomy or minor surgical applications. It can be used for nasal, oral and tracheal aspiration of the body liquids (mucus, catarrh or blood) in the adult or in the children.
Blanco is designed to provide ease of transport and almost continuous use, obtained thanks to the adoption of an electronic system for power management.
The LED light on the front panel indicates the activation of the device and its state of charge (if any).
Made of highly heat resistant, electrically insulated plastic material in conformity with the latest European safety standard, the product is supplied with a complete polycarbonate sterilizable jar with overflow valve and it is equipped with aspiration regulator and vacuum indicator located on the front panel.

3.2 Main components

1. Antibacterial filter
2. Silicone tubes 8 x14 mm
3. LED indicator (if present)
4. Vacuummeter
5. On/off switch
6. 1000 cc Jar
7. Adjustment knob
8. Conical connection
9. Power supply (if present)
   NOT SHOWN IN PICTURE
10. European power cable (if present)
    NOT SHOWN IN PICTURE
11. 12 V cigarette lighter cable (if present)
    NOT SHOWN IN PICTURE

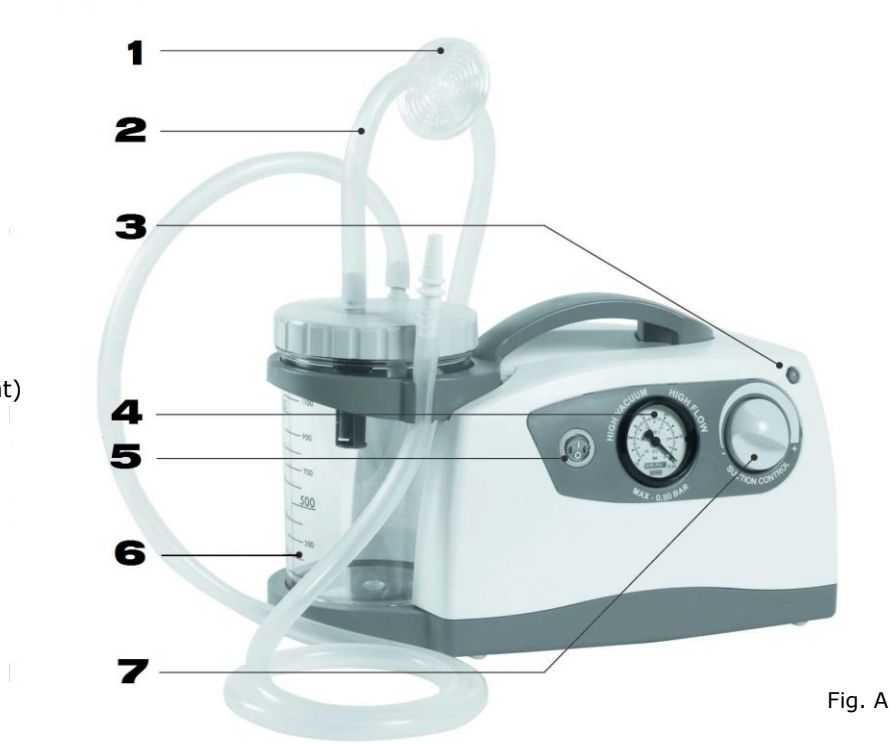


Fig. A

3.3 Models

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

SC10001B	Blanco – Portable suction pump 220 V, 16 L/min
SC10002B	Blanco – Portable suction pump 12 V, 16 L/min with battery
SC10003B	Blanco – Portable suction pump 12 V, 25 L/min
SC10004B	Blanco – Portable suction pump 220 V, 40 L/min
SC10005B	MOD.B014 Blanco 12 V 16 L/m with battery, power supply cable with plug
SC10007B	MOD.S024 Blanco 12V 16 L/min, white/red, with jar 1,5 L
SC10036B	Blanco - Portable suction pump 12 V / 220 V, 36 L/min with battery

3.4 Technical data

Model	SC10001B	SC10002B	SC10003B	SC10004B	SC10036B
Classification (according to Directive 93/42/CEE)	Medical Device Class IIa	Medical Device Class IIa	Medical Device Class IIa	Medical Device Class IIa	Medical Device Class IIa
Classification UNI EN ISO 10079-1	High vacuum/ Low flow	High vacuum/ Low flow	High vacuum/ High flow	High vacuum/ High flow	High vacuum/ High flow
Power supply	230 V ~/ 50 Hz	14 Vcc 4 A with power pack AC/DC mod. UE60-140429SPA3 (input: 100-240 V**~ -** 50/60 Hz – 100 VA) supplied or internal power supply (PB battery 12 Vcc 4 A) or by cable car cigarette lighter (12 Vcc 4 A)	12 V DC	230 V ~/ 50 Hz	14 Vcc 4 A with power pack AC/DC mod. UE60-140429SPA3 (input: 100-240 V**~ -** 50/60 Hz – 100 VA) supplied or internal power supply (PB battery 12 Vcc 4 A) or by cable car cigarette lighter (12 Vcc 4 A)
Power consuption	184 VA	50 VA	40W	110 VA	4.0A
Maximum aspiration (without jar connection)	-75 kPa (-0,75 Bar)	-75 kPa (-0,75 Bar)	-75 kPa (-0,75 Bar)	-80 kPa (-0,80 Bar)	-80 kPa (-0,80 Bar)
Minimum aspiration (without jar connection)	Lower than -40 kPa (-0.4 bar)	Lower than -25 kPa (-0.25 bar)	Lower than -25 kPa (-0.25 bar)	Lower than -40 kPa (-0.4 bar)	Lower than -40 kPa (-0.4 bar)
Maximum aspiration flow (without jar connection)	16 L/min	16 L/min	25 L/min	40 L/min	36 L/min
Isolation class (when used with AC / DC adapter included)	Class II	Class II	Class II	Class II	Class I
Isolation class (when used with internal battery)	/	Internally Powered Equipment	/	/	Internally Powered Equipment
Isolation class (when used with cigarette lighter cable)	/	Class II	Class II	/	Class II
IP Protection	IP 21	IP 21	/	IP 21	IP 21
Weight	2,5 kg	3,5 kg	2,5 kg	3,60 kg	4,39 kg
Dimensions	350 x 210 x 180 mm	350 x 210 x 180 mm	350 x 210 x 180 mm	350 x 210 x 180 mm	350 x 210 x 180 mm
Battery life	/	80 minutes	/	/	60 minutes
Battery charging time	/	240 minutes	/	/	240 minutes
Readability vacuum indicator	±5%	±5%	±5%	±5%	±5%
Fuse	F 1 x 1.6 A L 250 V	F 1 x 630mA L 250V	F 10A L 250V	F 1 x 1.6A 250 V	F 10A L 250V
Functioning	Continuous	Continuous	20 min on 40 min off	Continuous	60 min ON
Conformity Reg.10	/	Yes	/	/	/

3.5 Environmental conditions

Functioning temperature: from +5 to +35 °C
Functioning humidity: from 10 to 93%
Functioning altitude: from 0 to 2000 m above sea level
Storage temperature: from -25 to +70 °C
Storage humidity: from 0 to 93%

3.6 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive for Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive regarding active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Decreto Legislativo 24/02/1997, n. 46	Application of the 93/42/CEE Directive for Medical Devices
Decreto Legislativo 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1 /Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans
ISO 10079-1	Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements
CEI EN 60601-1-6	Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Usability
EN 60601-1	Medical eletrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical eletrical equipment – Part 1: General requirements for safety; collateral standard – Electromagnetic compatibilità – Requirements and test
EN 50419	Marking of electrical and electrical equipment in accordance with Article 11 (2) of Directive 2002/96/EC (WEEE)
ISO 10993-1	Biological evaluation of medical device – Part 1: evaluation and testing
ECE R-10	Regulation 10 - European Directive 95/54/EEC and international regulations ECE-R10

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

On receipt of the product:

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

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

On opening the packaging and before each use, check the integrity of the device, paying particular attention to the presence of damages to the plastic parts, which could make accessible internal parts under tension, and cause breakage and/or peeling of power cable. In such cases do not connect the plug to the power outlet. Before connecting the appliance, always check that the electrical data shown on the label and the type of plug used correspond to those of the electrical network to which you want to connect.

If the plug supplied with the unit is incompatible with the AC outlet, contact qualified personnel to replace the plug with a suitable type. In general, it is inadvisable to use adapters, multiple sockets and/or extensions. If their use was essential, you should use those in compliance with safety standards, while pointing careful not to exceed the maximum power supply, which are indicated on the adapters and extension cords.

4.3 Functioning

4.3.1 Functioning with AC / DC adaptor (where present)

- Connect the short silicone tube with the antibacterial filter to the suction connector. The other tube, with one end connected to the filter must be connected with the other end to jar's lid connector where has been fixed the float (overflow device). When the 90% of the volume of the jar is reached there is the activation of the security overflow device (the float closes the aspiration connector on the jar) to avoid liquid penetration inside the device. The device must be used on a plan of horizontal operation.
- Connect the long silicon tube to the other jar's lid connector. Connect the other end of the long silicon tube to the probe plastic connector then connect the suction probe to it.

- Connect the universal adaptor to the device via the appropriate connector and plug the power cord into the power outlet. To start treatment, press the switch to the I position to turn on. Set the desired vacuum (Bar/kPa) through a special vacuum regulator. Turning the knob clockwise gives higher value of vacuum: these values can be read on the instrument "vacuummeter".
- To suspend and / or terminate the treatment, press the switch again and pull out the plug from the power outlet.
- To avoid the formation of foam inside the collection jar, unscrew the jar's lid and fill the jar 1/3 full or ordinary water (this for an easy cleaning operations and an rapid reaching of the functionally vacuum) then rescrew the lid on the jar correctly.
- Take out the accessories and proceed to cleaning as described in chapter "Cleaning".

The side of the protection filter labelled "IN" must always be connected to the suction aspirator.
The wrong connection causes the immediate destruction in case of contact with the liquid aspirated.

4.3.2 Functioning with 12 V DC cigarette lighter cable (if present)

- Connect the cable through the cigarette lighter socket 12 V external unit with the cigarette lighter socket.

Check the state of charge of the battery of the vehicle prior to use the device with the cigarette lighter cable.

- Press the switch to the I position to turn on the suction device.

Use only the original cigarette lighter power adapter provided by the manufacturer.

4.3.3 Functioning with internal battery (if present)

- Press the switch to the I position to turn on the device (the external power supply must not be connected).
- The battery when fully charged will last about 60 minutes with continuous operation.

Before using the device check the state of charge of the lead battery.
Before each use, proceed with the charging of the battery.
To maintain a good state of the device recharge the battery every 3 months (if not in use).

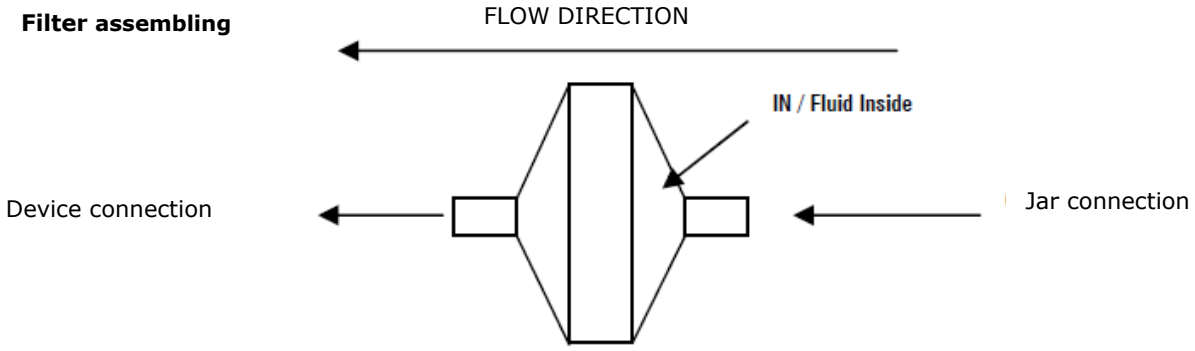
Recharge operations: In order to charge the internal battery, connect the universal power adapter (supplied) to the power supply for the time indicated in the paragraph "technical data" with the switch on position 0.

4.3.4 Light signals during functioning (when present)

With external power (regardless of the state of charge of the battery) when the device is in operation (after pressing the power button), the LED remains lit SOLID GREEN.

LED signal	Phase	Problem/Cause	Remedy
Flashing green LED	During charging	Battery charging in progress	Wait
Solid green LED	During charging	Charging cycle finished	Disconnect the power supply
Solid red LED	During battery functioning	Low battery warning	Start charging cycle
Flashing red LED	Automatic shutdown due to low battery	Fully discharged battery	Provide with the charging cycle of the battery
Solid orange LED	During battery functioning	Battery not fully charged	At the signal of the red LED, start a charging cycle

4.3.5 Filter assembling



If the conditions of the protective conductor system to which you connect the medical device in question appear to be dubious, we recommend using the equipment with its own internal battery.
The filter is made of hydrophobic material and blocks the passage of liquids that come into contact with it.
Always replacement it if you suspect it might be contaminated and/or wet or discolored.
If the suction device is used on patients in unknown pathological situations and where it is not possible to check any indirect contamination, replace the filter after each use.
In the case it is known that the patient's pathology and/or if there is no risk of contamination, we recommend changing the filter after every shift or every month even if the device is not used.

Never use the device without the jar and/or without protective filter.

<u>This section contains information about the compliance of the device to IEC 60601-1-2 norm.</u>
The surgical aspirator model ASKIR 36BR is an electromedical device that needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. RF communications

equipment, mobile and portable (cell phones, transceivers, etc.) may affect the medical system. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the device and the system as replacement parts, can result in increased emissions or decreased immunity of the device or system.

For all models of the Blanco Series:

Guidance and manufacturer's declaration – electromagnetic Emissions		
The surgical aspirator BLANCO is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator BLANCO should assure that it's used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The surgical aspirator BLANCO only used RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not cause interference in proximity of any Electronic appliances.
Irradiated / Conducted emissions CISPR11	Class [B]	The surgical aspirator BLANCO can be used in all environments, including domestic and those connected directly to the public mains distribution that supplies power to environments used for domestic scopes.
Harmonic emissions EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator BLANCO is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator BLANCO should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6kV on contact ± 8kV in air	The device doesn't change its state	Floors should be wood, conceret or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4	± 2kV power supply lines ± 1kV for input / output lines	The device doesn't change its state	Mains power quality should be that of a typical commercial environment or hospital.
Surge EN 61000-4-5	± 1kV differential mode	The device doesn't change its state	Mains power quality should be that of a typical commercial environment or hospital.
Loss of voltage, brief voltage interruptions and variations EN 61000-4-11	5%U_T (>95% dip U_T) for 0.5 cycle 40%U_T (>60% dip U_T) for 5 cycle 70%U_T (>30% dip U_T) for 25 cycle <5%U_T (>95% dip U_T) for 5 sec	-	Mains power quality should be that of a typical commercial environment or hospital If the user of the surgical aspirator BLANCO request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field EN 61000-4-8	3A/m	The device doesn't change its state	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Nota U_T is the value of the power supply voltage			

Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator BLANCO is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator BLANCO should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted Immunity EN 61000-4-6	3Vrms 150kHz to 80Mhz (for non life-supporting devices)	V_1 = 3 V rms	The portable and mobile RF communication devices, including cables, must not be used closer to the BLANCO device, than the separation distance calculated by the equation applicable to the transmitter frequency. Recommended separation distance d = [3.5 / V_1] $\sqrt{P}$ d = [12 / E_1] $\sqrt{P}$ from 80 MHz to 800MHz d = [23 / E_1] $\sqrt{P}$ from 800 MHz to 2.5 GHz Where P is the maximum nominal output voltage of the transmitter in Watt (W) depending on the manufacturer of the transmitter and the recommended separation distance in metres (m). The intensity of the field from the fixed RF transmitters, as determined by an electro-magnetic study of the site[a)], could be lower than the level of conformity of each frequency interval [b)]. It is possible to check for interference in proximity to devices identified by the following symbol:
Radiated Immunity EN 61000-4-3	3V/m 80MHz to 2.5GHz (for non life-supporting devices)	E_1 = 3 V / m	
Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by reflection from buildings, objects and people. a) The field intensity for fixed transmitters such as the base stations for radiotelephones (mobile and cordless) and terrestrial mobile radio, amateur radio devices, radio AM and FM transmitters and TV transmitters can not be theoretically and accurately foreseen. To establish an electro-magnetic environment generated by fixed RF transmitters, an electro-magnetic study of the site should be considered. If the field intensity measured in the place where the device will be used surpasses the above mentioned applicable level of conformity, the normal functioning of the device should be monitored. If abnormal performance arises, additional measures such as changing the device's direction or positioning may be necessary. b) The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 3 V/m.			

Recommended separation distance between portable and mobile radio-communication devices and the monitor			
BLANCO surgical aspirator is intended to operate in an electro-magnetic environment where RF irradiated interferences are under control. The client or operator of the BLANCO device can help prevent electro-magnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and the BLANCO device, as recommended below, in relation to the radio-communication maximum output power.			
Maximum nominal output power of the Transmitter W	**Separation distance from the frequency transmitter (m)**		
	150 kHz to 80 MHz $d = [3.5 / V_1] \sqrt{P}$	80 MHz to 800 MHz $d = [12/E_1] \sqrt{P}$	800 MHz to 2.5 GHz $d = [23/E_1] \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters with a maximum nominal output power not shown above, the recommended separation distance in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the maximum nominal output power of the transmitter in Watt (W) depending on the transmitter's manufacturer. Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by the reflection from buildings, objects and people.			

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Solid red LED (where present)	Low battery	Connect the power cord to the power supply, with switch on "O"
No LED is lit (if any)	Device blocked	Bad power supply or internal technical problem: contact the service centre
No aspiration	Jar lid wrongly screwed	Loosen and tighten up the lid of the jar
	Lid seal out of the correct place	Unscrew the cover and insert the seal into the correct place
The float is blocked	The float it's covered by dirty material	Unscrewed the cap, leave the and put in on autoclave
The float doesn't close	If the cap was washed verify that the float has not been partially detached	Fix the float
Low suction	Foam inside the collection jar	Fill the jar to 1/3 full of ordinary water
No aspiration due to flow leakage of mucus	Filter blocked	Replace filter
The suction device does not work	• Faulty power cord • Source of aspiration fails and/or absent	• Replace the power cord • Check the power source and voltage values
Vacuum power is low or absent	• Vacuummeter is open • Protection filter is blocked • Connection pipes to the filter and the device are clogged, bent or disconnected • Overflow valve closed or blocked • The pump is damaged	• Fully close the regulator and control the vacuum power • Changing the filter • Connect the hoses to the filter and/or jar or replace if clogged • Unlock the overflow valve, hold the device in a vertical position • Contact Spencer Italia S.r.l. technical service
Noisy device	Internal problem	Contact Spencer Italia S.r.l. technical service
Problems 1-2-3-4-5-6-7-8-9-10	**None of the remedies was effective**	**Contact the distributor or Spencer Italia S.r.l. service center**

If the overfill security system it's activated, don't procede with the liquid aspiration.
If the overfill security system doesn't work there are two cases:
1st case: If the overfill security system doesn't work the aspiration will be stopped by the bacteriological filter who avoid the liquid penetration inside the device.
2nd case: If both the security system doesn't work, there is the possibility that liquid comes inside the device, in this case return the device to Spencer Italia S.r.l. technical service (paragraph 1.4).

Before performing any checks in the case of anomalies or malfunctions, contact the technical service. The manufacturer does not offer any kind of guarantee for the equipment that occurs tampered with as a result of the technical service prove.

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 ti 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 the main unit

To clean the device, use a soft, dry or slightly damp cloth. Do not use abrasive cleaning agents and solvents. Never wash the device under running water or by immersion.

Pay special attention to make sure that the internal parts of the device do not come in contact with liquids and which power supply or battery are disconnected before to start cleaning the device.

5.2 Cleaning the components

The washing and/or cleaning of the autoclavable jar must be made according to this scheme:
- Wear gloves and protective apron (if necessary goggles and face mask) to avoid contact with any contaminants
- Disconnect the device from the jar
- Disconnect all hoses from the jar and protection filter
- Empty and dispose of the contents of the bottle and the suction catheter as required by local laws and regulations
- Separate all parts of the lid (overflow device, seal).

Dispose of disposable parts and disassembled the bottle, soak in cold running water and rinse well. Following immerse the same in hot water (temperature not exceeding 60 °C). Wash thoroughly, and if necessary, use non-abrasive brush to remove any deposits. Rinse with warm running water and dry all parts with a soft cloth (non-abrasive). And 'possible to autoclave the accessories lid and jar: insert the parts in autoclave and carry out a sterilization cycle with steam at a temperature of 121 ° C (relative pressure 1 ba - 15 min) taking care to position the graduated jar upside down (with the bottom facing upwards).
The mechanical strength of the container is guaranteed up to 30 cycles of cleaning and sterilization under the conditions specified (EN ISO 10079-1). Beyond this limit may occur decays of the physico-mechanical properties of the plastic and therefore the replacement is recommended.
After sterilization and cooling of the components to the ambient temperature, make sure that the latter would not be damaged, then reassemble the container for liquids sucked by following the following steps:
- Take the lid and place the floating support in the seat (under the connector VACUUM)
- Insert float cage and float with the seal facing towards the opening of the cage
- Place the seal in place on the cover
- After reassembly, always make sure of proper closing of the lid to prevent vacuum leaks and spillages of liquids.

The suction hoses transparent silicone can be placed in an autoclave where to perform a sterilization cycle at a temperature of 120 °C (relative pressure ba 1 - 15 min). The conical fitting (which is supplied together with the suction tubes) can be sterilized at a temperature of 121 °C (relative pressure 1 bar - 15 min).
Do not never wash, sterilize or autoclave the antibacterial filter.

5.3 Maintenance

5.3.1 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 is either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

The device does not need maintenance or lubrication, but it is necessary to check functioning and safety of the instrument before every use.
Unpack the instrument and always check integrity of plastic parts and AC/DC feeding cable (if present), because they might have been damaged during previous use.
Connect cable to electrical network and turn switch on. Close the aspirator outlet with your finger and with suction regulator in maximum vacuum position check that the vacuum indicators reaches –85 kPa (-0.80 bar). Rotate the knob from right to left and check the aspiration regulating control. The vacuum indicator should go down -40 kPa (-0.40 bar).
Verify that loud noises are not present, these can indicate wrong functioning.
A protection fuse not accessible from outside is situated in the plug to protect the instrument. For fuse replacing, always contact a qualified technician authorized by manufacturer.
The device has a lead battery (if present) not accessible from outside. For replacement, contact a qualified technician authorized by manufacturer.

5.3.2 Periodic maintenance

The device must be serviced by the manufacturer or by an authorised centre, **every year**.
If the correct revision is not carried out, the device MUST BE PUT OUT OF SERVICE, because the CE branding will no longer be considered valid and consequently the device will be no longer compliant with the safety standards declared by the manufacturer at time of purchase.
Spencer Italia S.r.l. will take no responsibility for the incorrect functioning or any damage caused by a device that has not undergone regular revision.
For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

5.3.3 Special servicing

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.
For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding operations carried out on the device.

5.3.4 Life span

The device, if used as indicated in the instruction manual, has an average life span of 5 years starting from the purchase date. If, for any reason, is not possible to trace the purchase date, the life span starts from the manufacturing date.
The life span can be extended for up to another 5 years, only if the device has been revised every year with positive result.
General revisions must be carried out by the manufacturer or by a centre authorized by the manufacture. If such annual revisions are not carried out, the device MUST BE DISPOSED AND THIS EVENT MUST BE NOTIFIED TO THE MANUFACTURER.
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 serviced by the manufacturer or authorized center, or of any device for which the life span is expired.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

SC10012B	Fixation system 10 G for suction device
SC10013B	Fixation system for suction device
SC10014C	Transport bag for suction device
SC70086A	Autoclavable 2000 cc jar
DG00212C	Aspiration catheter
DG00150A	Yankauer rigid cannula
DG00151A	Yankauer rigid cannula with suction control

6.2 Spare parts

SC10010E	Power supply 12 V cigarette lighter cable
SC10011E	Power supply cable 220 V AC
SC10037C	Spare filter for SC10036
SC70085A	Autoclavable 1000 cc jar
SC70087A	Lid for vase with overflow valve
SC70088A	Disposable conic connector
OX10105A	Silicone tube 8 x 14 mm
OX10107C	Silicone tube for aspirator diam. 6x10 mm
RV71106C	VP filter - filter for aspirators blanco ø 7,5 mm

ATTACHMENT A – TRAINING REGISTER

The product must be used only by trained personnel who have attended specific training for the use of this device and just for products with similar characteristics.

Keep this document at least 10 years after 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		

ATTACHMENT B – MAINTENANCE REGISTER

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

Perform the required maintenance and to respect the life span 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)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (Operator/ Authorized centre/ Manufacturer)