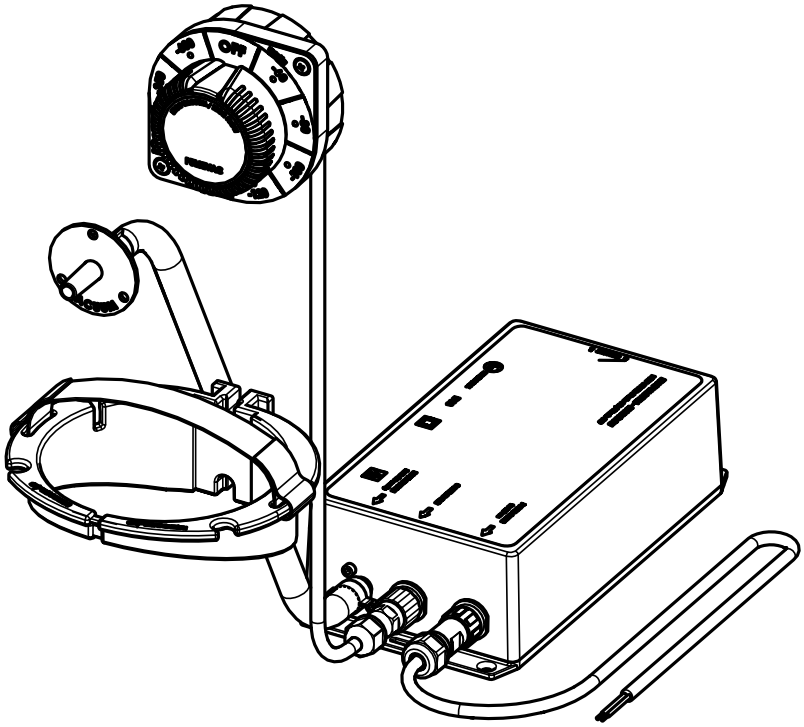
Instructions for use

# PulseVac
# Fixed suction device



The image is purely indicative and may not fully reflect the characteristics of the product

CE 0051

**Spencer Italia s.r.l.** – Via Provinciale n° 12 – 43038 Sala Baganza (PR) - Italy

**Notice**

The information in this manual is subject to change without notice.

The images are included as examples and may vary slightly from the actual device.

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Quality System EN ISO 9001 – EN ISO 13485

# CONTENTS

## 1. MODELS

This document applies to the following references:
SC20000 - PULSEVAC FIXED SUCTION DEVICE
SC20001 – MOD.O004 PULSEVAC FIXED SUCTION DEVICE
SC20002 – MOD.M011 PULSEVAC FIXED SUCTION DEVICE
SC20003 - MOD.M020 PULSEVAC FIXED SUCTION DEVICE

**The above mentioned variants can be subject to implementation or change without notice.**

## 2. INTENDED USE

### 2.1 INTENDED USE AND CLINICAL BENEFITS

PulseVac is a fixed suction device used to remove body fluids such as mucous, vomit or blood for therapeutic purpose. The device is intended to be permanently installed inside a road ambulance.

### 2.2 TARGET PATIENTS

There are no particular indications related to the patient group.

### 2.3 PATIENT SELECTION CRITERIA

The device does not have its own patient selection criteria. The selection depends on the need to clear airways and this could be necessary in any patient. The selection is related to suction accessories (suction cannulas or catheters) to be used.
Cannulas and catheters are not part of the device.

### 2.4 CONTRAINDICATIONS AND SIDE EFFECTS

The device does not have absolute contraindication, but there are conditions in which particular precaution will be taken as for example Hypoxia, patient distress, laryngospasm or severe bronchospasm, acute head, facial or neck injury. In such cases application of suction shall be evaluated with the responsible person in charge.

### 2.5 USERS AND INSTALLERS

Intended users are doctors, paramedics or nurses trained for the use of the device and in suction procedures.
Intended installers are typically ambulance builders.
Operators using the device should be physically able to use the device. Operators' ability must be assessed before the definition of roles in use of the device.
Operators must be able to provide the necessary patient care
These devices are not intended for lay people.

PulseVac is a device intended for professional use only. Do not allow untrained persons to help while using the product, as they may cause injury to themselves or others.
Despite all efforts, laboratory tests, trials, and instructions for use, standards do not always reproduce practice, so the results obtained under actual conditions of product use in the natural environment may sometimes differ significantly.
The best instructions are the continuous practice of use under the supervision of competent and trained personnel.

Operators using the device should be physically able to use the device. Operators' ability must be assessed before the definition of roles in use of the device.

**Operators must be able to provide the necessary patient care.**

#### 2.5.1 USER TRAINING

- Regardless of your level of experience with similar devices in the past, you should carefully read and understand the contents of this manual before installing, operating, or servicing this product. In case of any questions, please contact Spencer Italia S.r.l. for the necessary clarifications.
- The product must be used only by personnel trained in the use of this product and not on other similar products.
- The suitability of the users for use of this product can be attested by the training registration, in which trained persons, trainers, date and place are specified. **This documentation must be kept for at least 10 years after the end of the product's life and must be made available to the competent authorities and/or the Manufacturer when requested. In the absence of such documentation, the relevant bodies will apply any foreseen sanctions.**
- Do not allow untrained people to help while using the product, as they may cause injury to themselves or others.
- The product must be put into use only by personnel trained in the use of this product and not on other similar products.
- Training must be recorded for all personnel involved in the use of the device in all phases of its life cycle. This training must be periodically renewed. The training must be carried out by personnel with proven knowledge in the use and maintenance of the device.

***Note: Spencer Italia S.r.l. is always available for training courses.***

#### 2.5.2 INSTALLER TRAINING

The installer of the device must be able to ensure that all equipment, systems, containers and connections comply with all applicable safety requirements and standards. This implies knowledge of all applicable regulatory requirements and standards.

The installer should:

- Ensure proper installation of devices inside the ambulance
- Ensure that during installation phases the device has been not damaged and does not come in contact with substances that could compromise safety of patient or operators.
- Ensure the suitability of connections according to the performances provided for the device
- Perform all post-installation test procedures as specified in this manual

## 3. REFERENCE STANDARDS

**As Distributor or End-User of the products manufactured and/or marketed by Spencer Italia S.r.l., users are strictly required to be familiar with the legal provisions in force in the country of destination of the goods, applicable to the devices to be supplied (including regulations relating to technical specifications and/or safety requirements) and, therefore, to understand the requirements necessary to ensure compliance of the products themselves with all legal requirements of the territory.**

| REFERENCE | DOCUMENT TITLE |
|---|---|
| EU Regulation 2017/745 | EU Regulation on Medical Devices |
| UNI EN ISO 10079-1:2022 | Medical suction equipment - Part 1: Electrically powered suction equipment |
| UNI EN ISO 10079-4:2021 | Medical suction equipment - Part 4: General requirements |
| IEC 60601-1+AMD1:2012 + AMD2:2020 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014+AMD1:2020 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |
| IEC 60601-1-12:2014/Amd 1:2020 | Medical Electrical Equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment |
| UNI EN 1789:2021 | Medical vehicles and their equipment - Road ambulances |
| Regulation 10 | Uniform provisions concerning the approval of vehicles with regard to electromagnetic compatibility |

## 4. INTRODUCTION

### 4.1 USING THE MANUAL

The purpose of this manual is to provide healthcare professionals with the information necessary for safe and appropriate use and maintenance of the device.

*Note: The Manual is an integral part of the device and therefore it must be kept for the entire life of the device and must accompany it in any changes of use or ownership. If any instructions for use for products other than the one received are present, please contact the Manufacturer immediately before use.*

Spencer products User Manuals can be downloaded from the site http://www.spencer.it or by contacting the Manufacturer. Exceptions are those items whose essentiality, reasonable and predictable use are such that it is not necessary to draw up instructions, in addition to the following warnings and indications on the label.

Regardless of your level of experience with similar devices in the past, it is advisable to carefully read and understand the contents of this manual before installing, operating, or servicing this product.

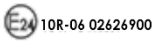
### 4.2 DEVICE LABELLING AND TRACEABILITY

Each device is provided with a label, placed on the device itself and/or on the packaging, which contains the Manufacturer's identification data, product, CE marking, serial number (SN) or lot number (LOT). This must never be removed or covered.

In the event of damage or removal, request a duplicate from the Manufacturer. Failure to do so, will render the warranty void as the device can no longer be traced.

**EU Regulation 2017/745 requires manufacturers and distributors of medical devices to keep track of their location. If the device is in a location other than the address to which it was shipped or sold, or if it was donated, lost, stolen, exported or destroyed, permanently removed from use, or if the device was not delivered directly from Spencer Italia S.r.l., please register the device at http://service.spencer.it, or inform Customer Service (see § 4.4).**

### 4.3 SYMBOLS

| Symbol | Meaning |
|---|---|
| CE 0051 | Device in compliance with EU Regulation 2017/745 |
| MD | Medical device |
|  | Manufacturer |
|  | Date of manufacture |
|  | Mandatory symbol “read instruction for use”. |
|  | Insulation class – Class II |
|  | Applied part – BF applied part |
| ⎓ | Direct current |
| **IP33** | Protection of enclosures for electrical devices<br>First digit: protection against ingress of particulate greater than 2.5 mm diameter<br>Second digit: Protected against Spraying water water with 60° angle |
|  | Approval number according to Regulation 10 |
|  | Warning for the correct disposal of the product according to the European Directive 2012/19/UE |
| LOT | Lot number |
| SN | Serial number |
| REF | Product code |

| | | | |
|---|---|---|---|
| UDI |  | Production identification<br>Alphanumeric code that identifies the production units of the device, composed of: | |
| | | (01)0805771123xxxx | company prefix (xxxx=GTIN) |
| | | (11) 200626 | date of production (YYMMDD) |
| | | (NN) 1234567890 | (NN)1234567890 NN=10 =>LOT/ NN=21=>SN |

### 4.4 WARRANTY AND SERVICE

Spencer Italia S.r.l. guarantees that products are free from defects for a period of **one year from the date of purchase**.

For information regarding correct interpretation of the instructions for use, maintenance, installation or return, please contact Spencer Customer Service tel. +39 0521 541154, fax +39 0521 541222, e-mail service@spencer.it.

To facilitate service, always indicate the lot number (LOT) or serial number (SN) on the label attached to the package or device itself.

**Warranty and service conditions are available at https://www.spencer.it.**

*Note:*

*Record and keep with these instructions: lot (LOT) or serial number (SN), if present, place and date of purchase, date of first use, date of checks, user name and comments.*

## 5. WARNINGS/DANGERS

Warnings, dangers, notes, and other important safety information are provided in this section and are clearly visible throughout the manual.

***Product features***

**Use of the product for any purpose other than that described in the User Manual is prohibited.**

- Before each use, always check the conditions of the product, as specified in the User Manual. In the event of faults/damage that could compromise its functionality/safety, remove immediately from service and contact the Manufacturer.
- If the product is found to be malfunctioning, use immediately a similar device to ensure continuity of ongoing operations. Non-compliant devices must be taken out of service.
- The product must not be tampered with or modified without the manufacturer's authorisation (modification, tweaking, additions, repair, use of non-approved accessories), as they may constitute imminent danger of injury to persons and material damage. Should these operations be performed, we decline any responsibility for incorrect operation or any damage caused by the product itself; moreover, the CE marking and the product warranty shall be null and void.
- Be sure to take every precaution to avoid hazards from contact with blood or body secretions, if applicable.
- Avoid contact with sharp or abrasive objects.
- For the use of fixed suction devices, it is recommended the adoption of an internal procedure or operational management which defines:

  a) Control of documents and records

  b) Training methods and related plans

  c) Responsibilities relating to preventive and extraordinary maintenance

  d) Definition of communication methods for personnel involved in the use and maintenance of the device.

***Storage***

- The product must not be exposed or come into contact with thermal sources of combustion or flammable agents and must instead be stored in a dry, cool place, away from light and sun.
- Do not store the product under other items no matter how heavy. They could damage the product.
- Store and transport the product with its original packaging, otherwise the warranty will be invalidated.

***Regulatory requirements:***

**As Distributor or End-User of the products manufactured and/or marketed by Spencer Italia s.r.l., users are strictly required to be familiar with the legal provisions in force in the country of destination of the goods, applicable to the devices to be supplied (including regulations relating to technical specifications and/or safety requirements) and, therefore, to understand the requirements necessary to ensure compliance of the products themselves with all legal requirements of the territory.**

- Promptly and in detail notify Spencer Italia s.r.l. (as from the quotation request phase) about possible fulfilments by the Manufacturer necessary for the compliance of products with specific legal requirements of the territory (including those deriving from regulations and/or regulatory provisions of another nature).
- Act with due care and diligence to help ensure compliance with the general safety requirements of the devices placed on the market, providing end-users with all the information necessary to carry out periodic revisions on the supplied devices, exactly as indicated in the User Manual.
- **Participate in safety checks on products** placed on the market, transmitting information regarding product risks to the Manufacturer as well as to the Competent Authorities for their respective actions.
- Without prejudice to the above, the Distributor or End-User shall assume wider liability related to non-compliance with non-fulfilment of the above-mentioned obligations, with consequent obligation to indemnify and/or hold Spencer Italia s.r.l. harmless from any possible injurious effect.
- With reference to EU Regulation 2017/745, please note that public or private operators who, when exercising their activity, detect an incident involving a medical product are required to notify the *Competent authority of the Member State in which the used and/or patient is established*, within the terms and in the manner established by one or more ministerial decrees, and notify the Manufacturer. Public or private health care professionals are required to notify the Manufacturer of any other incident that may allow the adoption of measures to ensure the protection and health of patients and users.

***General warnings for medical devices***

**The user must read carefully the following in addition to the general warnings.**

- Qualified personnel must be present during use of the device.
- Do not use if the device or parts of it are punctured, torn, frayed, or excessively worn.
- Follow the internal procedures and protocols approved by your organisation.
- Do not alter or modify the device arbitrarily, as doing so could result in unpredictable operation and damage to the patient or rescuers and shall void the manufacturer's warranty and release the manufacturer from all liability.

## 6. SPECIFIC WARNINGS

To use the device, you have must also read, understood and carefully follow all the instructions in the user manual.

- The device is intended to be used on medical vehicles and not for home therapy.
- Do not use if the device is damaged or is in poor cleaning conditions.
- To be used only by trained staff.
- Do not wash or clean the device with pressurized water or air.
- Do not use drying machines.
- Condensation, water, ice and dust accumulation can affect the proper operation of the device making it dangerous for patient and operators.
- Regularly check the fixation of the device and of its installation surfaces; if altered or damaged is necessary to restore their safety conditions before the use of the device. Otherwise we assume no responsibility on the improper functioning or any damage caused by the device itself.
- In the event of a malfunction of the device, suction therapy should be immediately restored by means of alternative devices able to carry out successfully and effectively such procedures.
- Before each use, check the integrity of the device as specified in the user's manual. In case of malfunction or damage that may compromise the functioning and safety of the device, patient or operator, it is necessary to put the device out of service and contact the manufacturer or a service center.
- During use, the assistance of qualified personnel must be ensured.
- Do not leave the patient without the assistance of at least one physician or practitioner with clinical experience of the ongoing therapy when the device is in use.
- The device should not be exposed to or come into contact with any source of combustion or inflammable agents.
- Do not store the device underneath any heavy objects which could cause structural damage.
- The device should be used in a ventilated environment.
- The use of the device in environmental and supply conditions other than those specified in this manual, will undermine the safety of operations and of the device itself.
- Do not lubricate any part of the device. It's not required by any kind of maintenance.
- Do not use the device if the safety conditions decribed in this manual are not met.
- Do not use the device if it has not been subject to scheduled maintenance or maintenance required by a normal use.
- Follow the maintenance program as specified by the manufacturer.
- Respect the maintenance and revision deadlines and the replacing of components described in this manual or provided by the manufacturer.
- Installation must ensure that operators can easily access all devices and their commands. If provided, it is necessary that all the information on the devices or reading of instruments are easily read by operators.
- Hoses should follow a linear pathway, avoiding flexions that could reduce the expected flow rates for the system.
- Use only accessories approved by the manufacturer.
- **Do not use the device for thoracic drainage**
    - Portable and mobile RF equipment can affect the operation of the device.
    - The installation and placing of the device must consider what is described in tables of paragraph 9 in order to ensure that the device maintains its basic safety and performance.
    - Use of cables or power supplies other than those approved by the manufacturer, can adversely affect the electromagnetic performance of the device.
    - The use of RF equipment, including antennas, can adversely affect the device. The fixed suction device or its supply cables should be kept away from other devices according to parameters listed in paragraph 9.
    - The use of accessories other than those approved by the manufacturer, may result in increased electromagnetic emissions or reduction of the immunity level of the device.
    - The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it is used.
    - Failure to follow warnings related to electromagnetic compatibility, can compromise the essential performance or basic safety of the device, affect the proper operation of components, affect the software, give unexpected change or behavior in suction, false indications.
    - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the device, including cables. Failure to observe this could degrade the performance of the equipment.
    - In order to maintain the basic safety and performance of the device, it is essential to check before and after each use, the integrity of the electrical connections and to verify that the environment in which the device is installed has not been changed for example by installation of additional devices.
    - The user must not have impairments that prevent proper reading and interpretation of information and proper operation of controls.
    - The installation must be performed ensuring appropriate distances between devices that could cause each other electromagnetic interference as specified in paragraph 9
    - In order to guarantee the performance of the device, it is necessary to use only cathethers, filter and suction tubes approved by the manufacturer (see section of accessories and spare parts).
    - Devices in direct contact with the patient shall be CE marked and shall be compliant with the requirements of UNI EN ISO 10993 series.
    - To ensure patient safety, the operator shall be trained in suction procedures
    - Do not carry out suction during insertion and extraction of the cathether
    - Always use gloves if there is the possibility of coming into contact with body fluids or contaminated objects
    - Clean carefully the hands after contact with mucous, respiratory secretions or objects contaminated with respiratory secretion, even if gloves have been used.
    - Before contact with another patient, replace gloves and wash the hands after touching secretions or contaminated objects

- Ensure that the ambulance electrical installation is compliant with the requirements described in this user manual and as required in the standard EN 1789. Connection to a power supply not compliant with such requirements will affect the proper operation of the device.
- If fluids have been suctioned without collection container or without filter or if a contamination of the suction circuit is suspected, immediately put the device out of service and contact a Spencer service center.
- The reuse of contaminated components or accessories, will cause serious risks of infection for patients and operators.
- The use in presence of flammable and/or anesthetic gas may cause fire risks

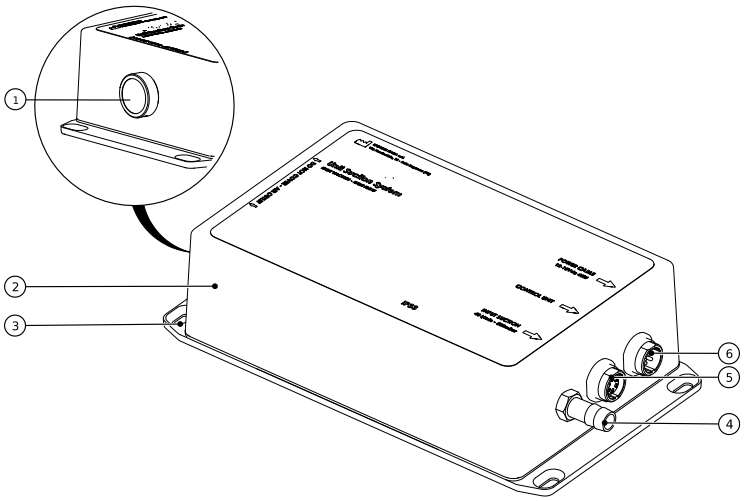
## 7. RESIDUAL RISK

The use of parts in contact with the patient (cannulas or catheters) that do not comply with biocompatibility requirements implies risk of physiological reactions, sensitization and/or skin irritation. Use only CE marked devices that comply with the requirements of ISO 10993.

## 8. TECHNICAL DATA AND COMPONENTS

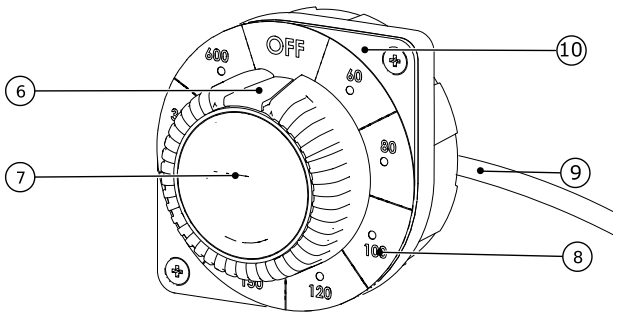
*Note: Spencer Italia s.r.l. reserves the right to make changes to specifications without notice.*

**Vacuum source**

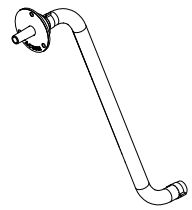
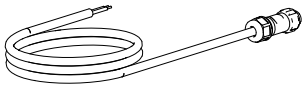
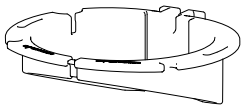


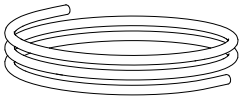
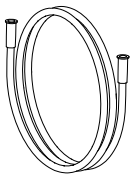
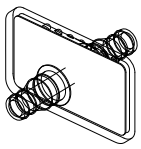
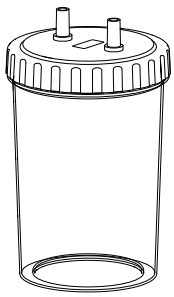
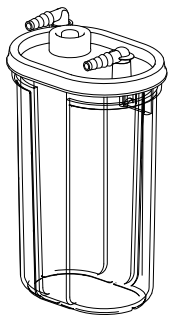

| Id | Description |
|---|---|
| 1 | Exhaust port – made of Aluminum, is the port from which air is discharged |
| 2 | Enclosure (vacuum source) – Made of ABS contains the vacuum pump and allows the installation of the device on a surface and is equipped with connectors |
| 3 | Fixation holes (the enclosure has 4 holes) |
| 4 | Aluminum hose holder to which the suction tube between vacuum source and collection container is connected |
| 5 | Control unit connector – Made of PC, is the port to which the control unit cable will be connected |
| 6 | Power supply connector – Made of PC, is the port to which the power supply cable will be connected |

**Control Unit**




| Id | Description |
|---|---|
| 6 | Knob position indicator – Made of red ABS provides a clear indication of the position in which the vacuum adjustment knob is placed |
| 7 | Vacuum adjustment knob – Made of ABS, can be rotated by the operator allowing the selection of the vacuum at the provided settings, selected by grades |
| 8 | Label with vacuum levels – Made of Polycarbonate has markings of the possible vacuum settings (60-80-100-120-150-200-350-600 mmHg) |
| 9 | Control unit cable – Sends the signal of the vacuum setting to the vacuum source |
| 10 | Panel – Made of stainless steel and covered with a polycarbonate label with led lights showing the vacuum level set |

| Detachable components | | |
|---|---|---|
|  |  |  |
| Connection hose with wall hose holder – Made of PVC with a conical aluminium anchored fitting, it is used to connect the vacuum source to the vacuum port intended for connecting the collection container. The device comes with 2 meter hose | Power supply cable – Made of PVC, it is used to connect the vacuum source to the power supply. A 2 meter cable with connector is supplied | Canister support – made of ABS, it will be mounted on the wall and is used to support the collection container. It is provided with a strap used to keep the collection container in place. The element can be mounted by means of two screws or attached on a clamp |

| Accessories | | | | |
|---|---|---|---|---|
|  |  |  |  |  |
| Connection hose – Made of silicone, used to connect the suction port on the wall to the input port of the collection container | Suction hose – Made of PVC, it is used to connect a suction cannula or catheter to the collection container. | Filter – Made of PC, it is placed in the proximity of the collection container on the tube coming from the vacuum source. The filter is disposable and to be used when the 1000ml reusable canister is used. Serres type canister does not require this filter because it is integrated in the lid | 1000ml Reusable collection container – Made of PC, it will be sterilized after each use. It can be sterilized up to 30 times. This canister requires the use of the disposable filter | 1000ml reusable canister with disposable bags – Made of PC and PE, has a rigid container in which the disposable collection bag which includes also the lid with integrated filter is placed. This canister does not require additional filters |

**Technical data**

| **DIMENSIONALS** | |
|---|---|
| Box length | 228 ± 1mm |
| Box width | 113 ± 1mm |
| Box height | 61 ± 1mm |
| Control knob group width | 88 ± 1mm |
| Control knob group height | 88 ± 1mm |
| Control knob group depth | 68 ± 1mm |
| Note: The installer shall consider that connection terminals applied to the box, increase the length of the device of 9/10 cm. | |
| **Weight** | |
| Control knob group weight | 360 g |
| Vacuum source weight | 910 g |
| **Power supply** | |
| Voltage | 12-15 Vdc (-15% + 25%) |
| Power consumption max | Max 60W |
| **FUSE** | |
| Internal resettable – not replaceable | |
| **VACUUM ADJUSTEMENTS** | |

| | |
|---|---|
| Control knob | Presets:<br>-60/-80/-100/-120/-150/-200/-350/-600 mmHg<br>(~ -80/107/133/160/200/267/467/800 mbar) |
| Precision | ± 10% at zero flow |
| **Other** | |
| Acoustic level | ≤ 70 db |
| **Classifications** | |
| Classification according to Regulation 2017/745/UE | IIa |
| Classification according to IEC 60601-1 | Class II |
| Applied part (Breathing tube, filter, connector, valve, mask) | The device has not applied part – the suction cannula should be considered a BF applied part |
| Suction performances according to ISO 10079-1 | HIGH VACUUM/HIGH FLOW |
| Enclosure protection according to IEC 60529 | IP33<br>First digit: protection against inlet of particulate greater than 2.5 mm diameter<br>Second digit: Protected against spraying water with 60° angle |
| Duty cycle | 50 min ON/ 10 min OFF |

**Environmental conditions**

- Storage and transport conditions
  a) Temperature from -40 to +70°C
  b) Humidity from 15% to 90%
  c) Atmospheric pressure from 620hPa to 1060 hPa

- Operating conditions
  a) Temperature from 0 to +40°C
  b) Humidity from 15% to 90%
  c) Atmospheric pressure from 620hPa to 1060 hPa

**Transient operating conditions**
- Temperature range of -20°C to +50°C
- a relative humidity range of 15% to 90%, non condensing, but not requiring a water vapour partial pressure greater than 50hPa

## 9. COMMISSIONING AND INSTALLATION

For first use, check that:
- Packaging is intact and has protected the device during transportation
- Check that all parts included in the packing list are present.
- General functionality of the device
- Product cleanliness

Do not modify the device or its parts for any reason as this could cause injury to the patient and/or rescuers.
Failure to take the above measures will preclude safe use of the device, resulting in risk of injury to the patient, operators and damage to the device itself.
If the above conditions are met, the device may be considered ready for use; otherwise, you must immediately remove the device from service and contact the Manufacturer.

Do not alter or modify the device arbitrarily, as doing so could result in unpredictable operation and damage to the patient or rescuers and will void the warranty and release the Manufacturer from all liability.

### 9.1 INSTALLATION

The installation of the device is a critical step to ensure proper operation.

The ambulance should have:
- A compartment suitable to fix and protect the vacuum source
- The device is designed to be used in the electromagnetic environment described below. The customer, installer and user must be able to ensure that these conditions are always respected.

| Guide and Manufacturer's Declaration | | |
|---|---|---|
| The fixed suction device is intended for use in the electromagnetic environment specified below. The customer or the user of the device must ensure that it is used in such an environment. | | |
| **EMISSION TESTS** | **Conformity** | **Guide to the electromagnetic environment** |
| Emissions in RF CISPR 11 | Group 1 | The fixed suction device uses RF energy only for its internal functions. Its RF emissions are therefore very low and unlikely to cause any interference with electronic equipment nearby. |
| Emissions in RF CISPR 11 | Class B | The fixed suction device is suitable for use in all environments including domestic as well as those directly connected to a low-voltage public network source supply of which supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | | |
| Emissions as a result of voltage fluctuations / flicker-IEC 6100 3-3 | Compliant | |

| Guide and Manufacturer's Declaration | | |
|---|---|---|
| The fixed suction device is intended for use in the electromagnetic environment specified below. The customer and / or user of the fixed suction device must ensure that the device is used in such environment. | | |
| **IMMUNITY TEST** | **Conformity level** | **Guide to the electromagnetic environment** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 8kV at contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air | Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should not exceed 30% |
| **Electrical fast transient/burst**<br>IEC 61000-4-4 | ± 2kV power supply<br>± 1kV for input/ouput lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Over voltage<br>IEC 61000-4-5 | ± 0.5 , 1kV for line to line surge<br>0.5, 1, 2kV for line to ground surge | Mains power quality should be that of a typical commercial or hospital environment |
| Voltage dips<br>IEC 61000-4-11 | 0 % UT; 0,5 cycles at 0°, 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% UT 1 cycle and 70% UT 25/30 cycles (25 at 50Hz and 30 at 60Hz)<br><br>Single phase at 0° | Mains power quality should be that of a typical commercial or hospital environment. If the user of the fixed suction device requires continued operation during power mains interruptions, it is recommended that the fixed suction device be powered from an uninterruptible power supply or a battery. |
| Voltage interruptions<br>IEC 61000-4-11 | 0% UT; 250/300 cycles | |
| Power frequency (50/60 Hz)<br>magnetic field<br>IEC 61000-4-8 | 30 A/m | Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment |
| note UT is the value of the tension of power source | | |

| Guide and Manufacturer's Declaration | | |
|---|---|---|
| The fixed suction device is intended for use in the electromagnetic environment specified below. The customer and / or end user of the fixed suction device must ensure that the equipment is used in such environment. | | |
| **IMMUNITY TEST** | **Level of conformity** | **Guide to the electromagnetic environment** |
| | | The equipment for communication in portable and mobile radio-frequency (RF) should not be placed near any part of the appliance, including cables etc. and should be kept at a distance which should never be less than that of the recommended and calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance |
| Conducted RF<br>IEC 61000-4-6 | 6 V<br>150kHz to 80MHz in ISM bands and amateur radio bands | $d = 0{,}583x\sqrt{P}$ |
| | 80% AM a 1khz | $d = 1{,}2\ x\sqrt{P}$ from 80Mhz to 800MHz |
| Radiated immunity CEI<br>EN 61000-4-3 | 10 V/m<br>80MHz to 2.7 Ghz | $d = 2{,}3\ x\sqrt{P}$ from 800Mhz to 2,7 GHz |

| | | |
|---|---|---|
| | | where P is the maximum rated power output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be at less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:  |

NOTE 1 At 80 MHz and 800 MHz the separation distance for the range of higher frequency is applied
NOTA 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot theoretically be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the fixed suction device is used exceeds the applicable RF compliance level above, the fixed suction device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the fixed suction device.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

**Recommended separation distances between portable and mobile communications equipment and the ventilator 190.**

The fixed suction device is intended for use in an electromagnetic environment in which radiated RF disturbance is controlled. The customer or the user of the fixed suction device may prevent electromagnetic interference by maintaining a minimum distance between the communications equipment radio frequency (RF) Portable and mobile equipment (transmitters) and the fixed suction device, as described below and in accordance with the maximum output power of the communication device

| Maximum output power rating of the transmitter | Separation distances according to frequency of transmitter (m) | | |
|---|---|---|---|
| (W) | From 150 kHz to 80 Mhz<br>Inside and outside ISM bands<br>$d = 0{,}583x\sqrt{P}$ | From 80 Mhz to 800 Mhz<br>$d = 1{,}2x\sqrt{P}$ | From 800 Mhz to 2,7 Ghz<br>$d = 2{,}3x\sqrt{P}$ |
| 0,01 | 0.058 | 0,12 | 0.23 |
| 0,1 | 0.184 | 0,38 | 0.73 |
| 1 | 0.583 | 1,2 | 2.3 |
| 10 | 1.844 | 3,8 | 7,3 |
| 100 | 5.83 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

| Guide and Manufacturer's Declaration | | |
|---|---|---|
| Immunity to proximity fields from RF wireless communications equipment | | |
| **Test Frequency (MHz)** | **Modulation** | **Immunity level (V/m)** |
| 385 | Pulse modulation[(1)] at 18Hz | 27 |
| 450 | FM[(2)] ±5Hz deviation 1kHz sine | 28 |
| 710 | Pulse modulation[(1)] at 217Hz | 9 |
| 745 | Pulse modulation[(1)] at 217Hz | 9 |

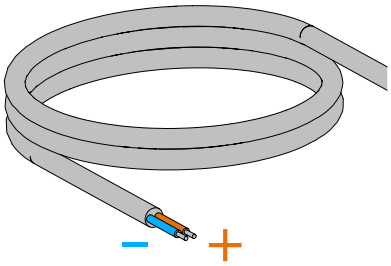
| | | |
|---|---|---|
| 780 | Pulse modulation(1) at 217Hz | 9 |
| 810 | Pulse modulation(1) at 18Hz | 28 |
| 870 | Pulse modulation(1) at 18Hz | 28 |
| 930 | Pulse modulation(1) at 18Hz | 28 |
| 1720 | Pulse modulation(1) at 217Hz | 28 |
| 1845 | Pulse modulation(1) at 217Hz | 28 |
| 1970 | Pulse modulation(1) at 217Hz | 28 |
| 2450 | Pulse modulation(1) at 217Hz | 28 |
| 5240 | Pulse modulation(1) at 217Hz | 9 |
| 5500 | Pulse modulation(1) at 217Hz | 9 |
| 5785 | Pulse modulation(1) at 217Hz | 9 |
| The carrier shall be modulated using a 50 % duty cycle square wave signal.<br>As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. | | |

- 

If the environmental conditions are appropriate, the device can be installed while verifying that:

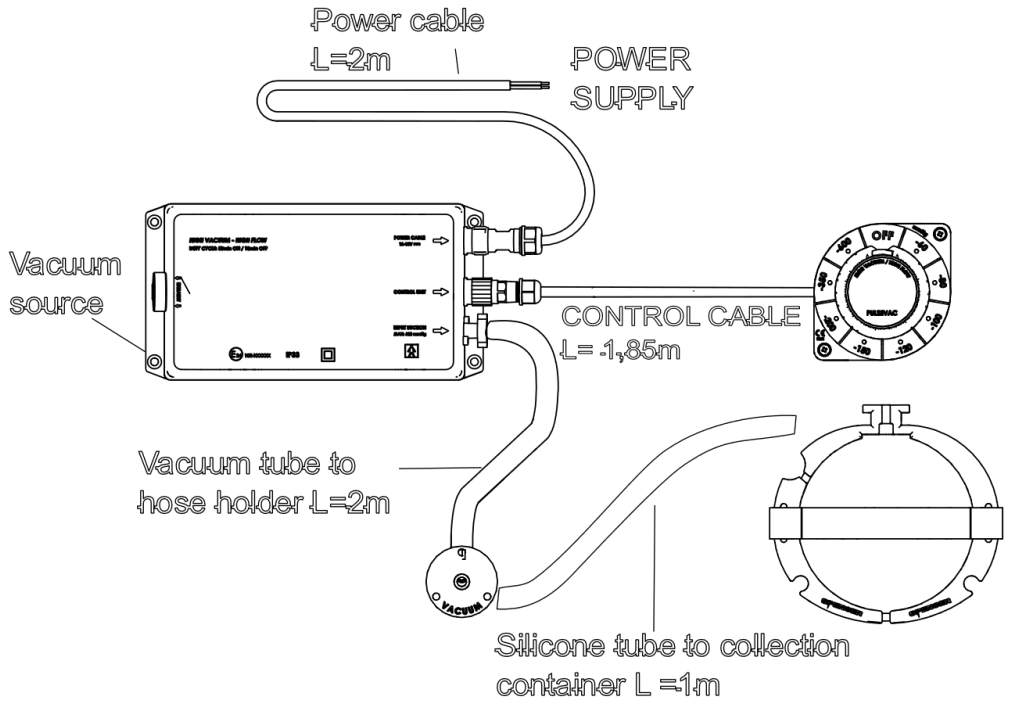
- The installation surface is level and strong enough to withstand accelerations and vibrations to which the device could be subjected during use on the medical vehicle. It's suggested the use of a backplate.
- The power supply system has been regularly serviced or, in case of initial startup, the periodic maintenance has been programmed.
- Verify that purchased accessories, if present, respect the same standard required for the use of the device, as for example biocompatibility requirements.
- Distances between other electrical and electronic devices are as described in this manual.
- The positioning of the device does not cause any type of obstruction inside the medical vehicle.
- The power supply has the characteristics described in this manual.
- The device must be installed insuring that the surfaces are strong enough to withstand the forces they may be subject to. Failure to do so, **precludes the safety and functionality of the device.**

The device must be connected to electrical power supply having the following characteristics:

| Power supply | |
|---|---|
| Voltage | From 12 to 15 V ⎓<br>(-15% + 25%) |
| Current Needed | > 5A |
| Power supply cables polarity |  |
| Brown – Positive<br><br>Blue - Negative | |

**Equip the electrical connection with a mains switch that allows you to remove power from the device.**

**The following diagram provides a useful representation to define the location of the various components inside the ambulance.**

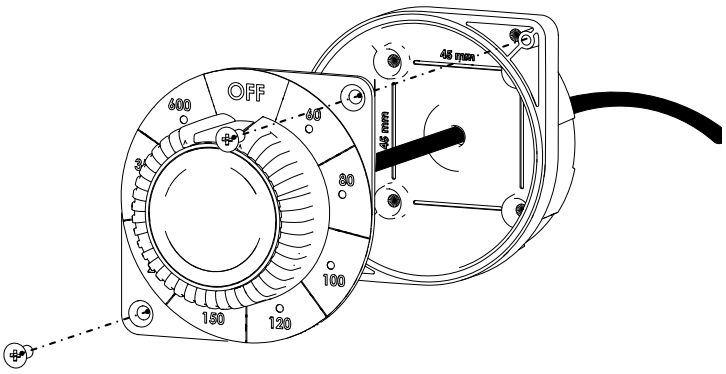



After having assessed the layout inside the ambulance, it is possible to proceed with the installation according to the following phases**:**

**STEP 1 – Installation of the control unit**

Regardless the version in use, it is necessary to drill holes on the wall in order to install the control panel.

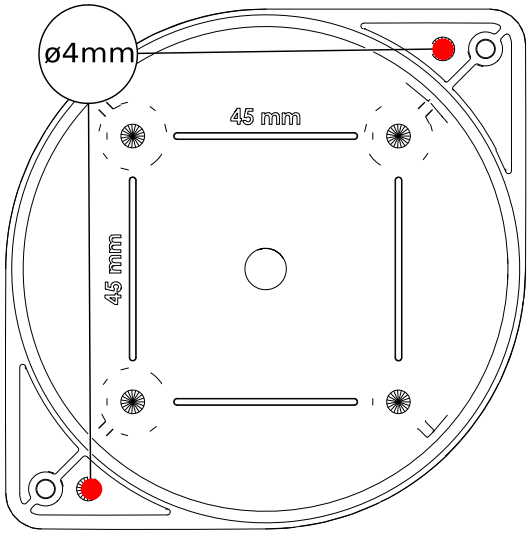
The device can be installed in the two ways described below:

| **Recessed mounting of the control unit** | |
|---|---|
| **Drill a ø 85 mm hole in the desired position on the wall**.<br>Positioning shall consider that the cable of the control unit has to reach the vacuum source unit easily and the cable shall not pass near sources of heat and other devices as described before | |
| Unscrew the bolts at the two opposite angles of the panel and slightly pull out the cable to provide easy access to the plastic enclosure.<br><br>**WARNING: DO NOT TOUCH THE ELECTRONIC BOARD TO AVOID DAMAGE TO THE CONTROL UNIT** |  |

Insert the plastic cover inside the ø85mm hole and drill ø4mm holes as shown in the picture.
The installation wall will also be drilled.

Fix the enclosure of the control unit using ø4mm TCEI bolts and self locking nuts with washer on the other side of the wall.
The length of the bolt depends on the thickness of the wall.

Mount again the panel with the knob on the plastic cover using the screws previously removed



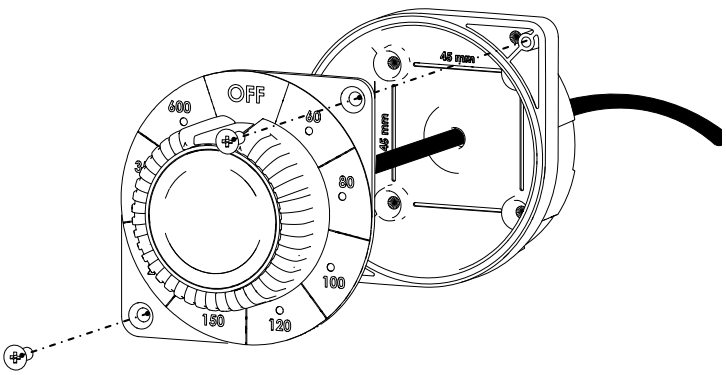

**Simple mounting of the control unit**

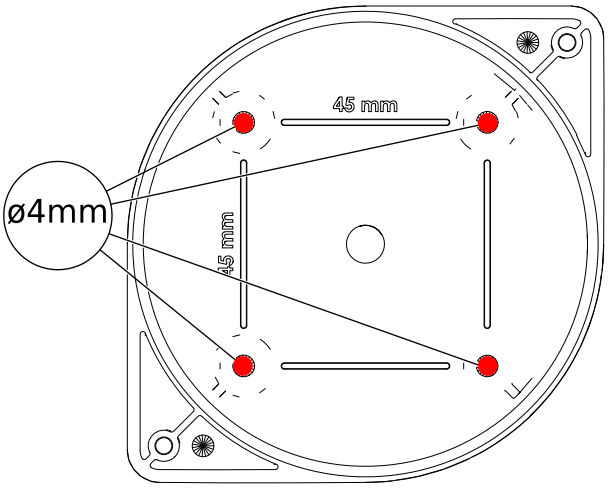
**Find a proper location on the wall and drill a ø25mm hole to allow the passage of the cable.**

Positioning shall consider that the cable of the control unit has to reach the vacuum source unit easily and the cable shall not pass near sources of heat and other devices as described before

Unscrew the bolts on the two opposite angles of the panel and pull the cable out a little to provide easy access to the plastic enclosure.

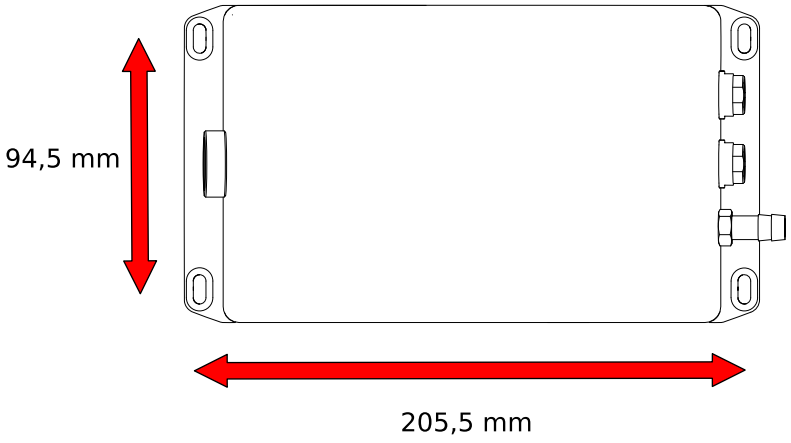
**WARNING: DO NOT TOUCH THE ELECTRONIC BOARD TO AVOID DAMAGE TO THE CONTROL UNIT**



| | |
|---|---|
| Make the cable pass through the ø25mm hole made on the wall and place the cover adherent to the installation surface.<br><br>Drill holes as shown in the picture.<br>Also the installation wall must be drilled.<br><br>Fix the enclosure of the control unit using ø4mm TCEI bolts and self locking nut with washer on the other side of the wall.<br>The length of the bolt depends on the thickness of the wall.<br><br>Re assemble the panel with the knob on the plastic cover. |  |

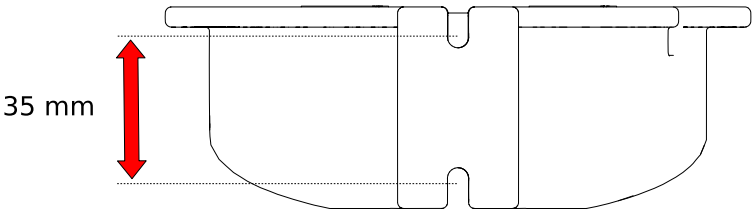
**STEP 2 – Installation of the vacuum source**

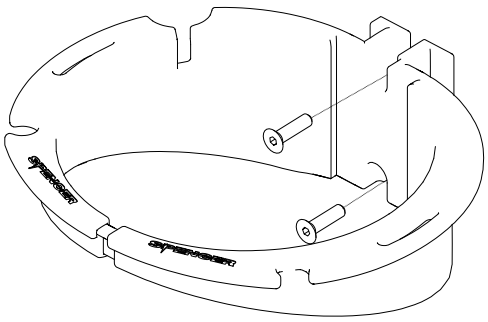
The suction source (pump body) of the device must be installed with the surface with label facing upwards, in a place inside the ambulance that guarantees adequate protection and free access for any inspection.
The fixing of this element takes place using the 4 holes present on the cover as identified in the picture, drilling ø4.5mm holes using the casing itself as a drilling template.
The vacuum source must be positioned at a distance that allows the silicone tube to easily reach the collection canister.




**STEP 3 – Installation of the canister support**

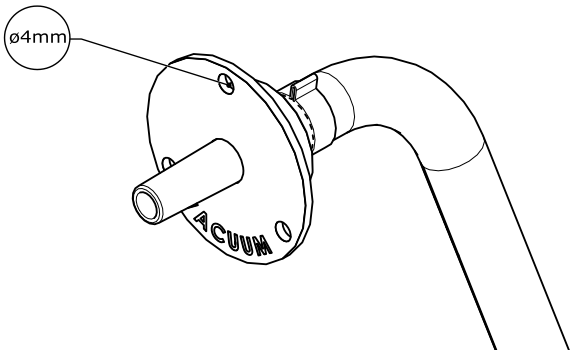
The canister support must be placed close to the patient. During positioning, consider the length of the tube provided for the connection between the canister and the vacuum source, as well as the length of the suction tube intended for the connection between the vessel and the suction catheter. The tubes must not be stretched and must not pass through areas that could compromise their integrity.
The canister support can be installed on the wall using two M5 screws with a length suitable to the thickness of the wall, which must adhere well to the slots in order to guarantee the stability of the support and, after being passed through the installation wall, must be anchored to the wall using washers and self-locking nuts.



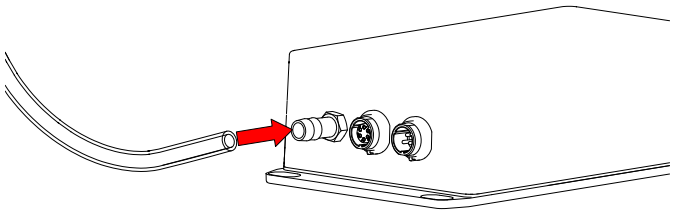
The canister support can also be anchored on a clamp compliant with UNI EN ISO 19054. In this case, follow the clamp manufacturer's instructions.

**PASSO 4 – Mounting of hose holder connection on the wall**




Connect the yellow hose to the rear fitting of the wall-mounted hose holder, bringing it up until the stop, then block it with the supplied clamp, tightening it with pliers. Make sure the connection is stable.
Drill a ø28mm hole on the wall at the point where you want to position the connection for the jar, taking into consideration that the length of the tube supplied does not allow you to position the suction unit at a distance more than 2 meters from the point of vessel connection.
It is possible to shorten the tube by cutting it to size. Reducing the length has positive effects on the performance of the device.
Insert the yellow tube inside the hole until it reaches the suction unit.
Fix the flange integrated into the hose holder using 3 ø4mm screws suitable for the installation surface.

**STEP 5 – Connection to the suction unit**

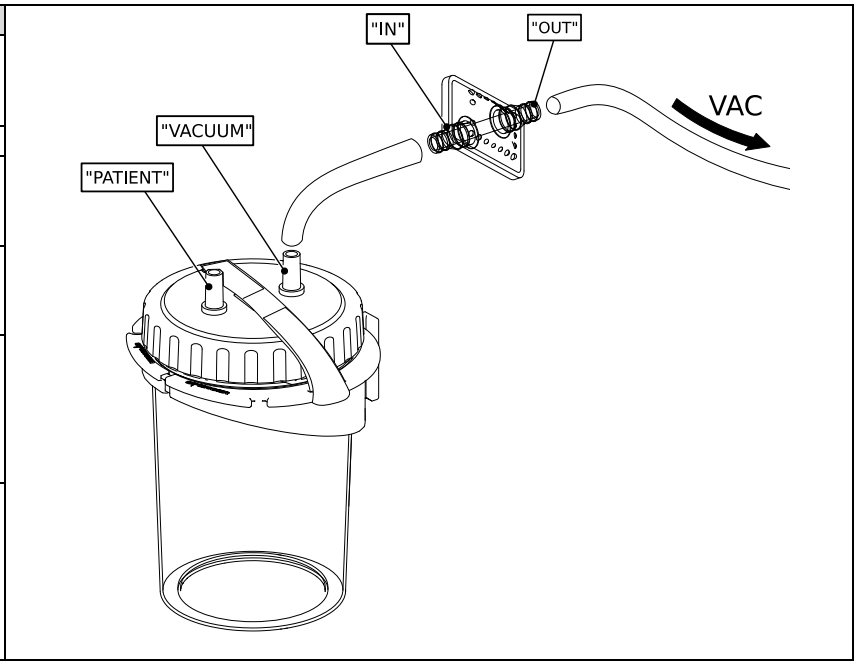


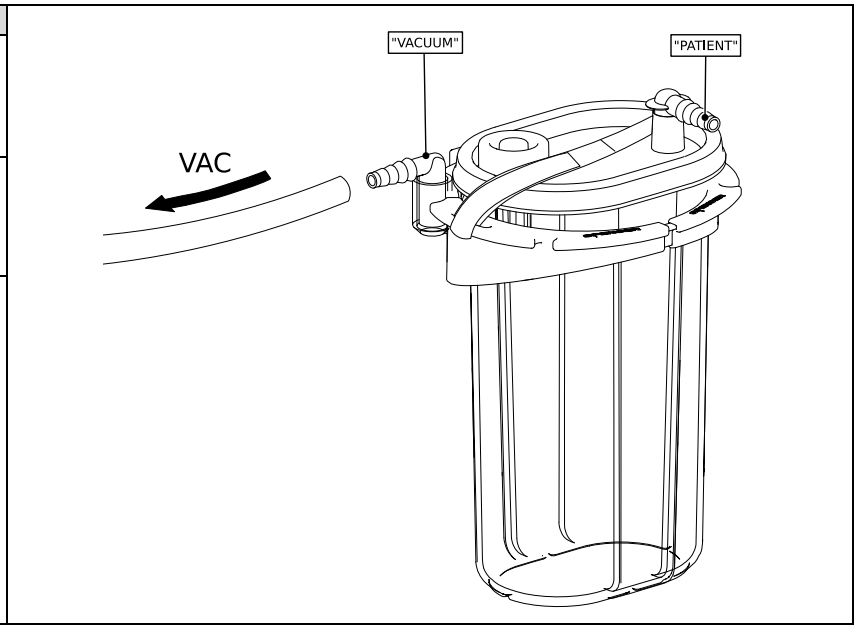
The suction unit is equipped with a hose holder identified by the wording “INPUT SUCTION”.
The yellow PVC pipe coming from the wall hose connection must be anchored to this hose holder.
Insert the hose until it stops at the base of the hose holder, then secure it to the hose holder using the supplied clamp with the aid of pliers.
Make sure the connection is stable.

**STEP 6 – Connecting the control unit and power cable**

Insert the 6-pole male terminal (A) of the control unit cable into the connector identified by the wording “CONTROL UNIT” and tighten the ring nut until it stops.
Insert the 3-pole female terminal (B) of the power cable into the connector identified by the wording “POWER CABLE”.
Ensure that the control unit is in position OFF, then connect to the power source compliant with the requirements previously described, respecting the connection polarity.

It is now possible to connect the collection container.
The table shows the correct connection depending on the canister used:

| **1000 ml reusable canister** |  |
|---|---|
| 1 – Place the canister in the canister support and secure it with the supplied strap | |
| 2 – Cut the last 15/20cm of the supplied silicone tube | |
| 3 – Connect the portion of pipe just cut to the connector identified by the wording “VACUUM” on the lid of the canister | |
| 4 – Connect the other end of the tube portion to the filter at the connector of the filter identified by the “IN” marking | |
| 5 – Connect the remaining portion of the silicone hose at one side to the filter connector identified with the “OUT” marking and at the other side, to the wall hose connection.<br>Make sure all connections are stable | |
| 6 – Only at the time of use, connect the patient suction hose to the connector identified by the “PATIENT” marking on the collection container. The catheter or cannula with which to carry out the suction operation must be connected to the free end of this tube | |

| **1000 ml Serres® Canister** |  |
|---|---|
| 1 – Place the canister in the canister support and secure it with the supplied strap | |
| 2 – Connect the silicone hose to the wall hose connection. At the other end, connect it to the gray rotating connector located on the jar | |
| 3 – Only at the time of use, connect the patient suction hose to the connector identified by the “PATIENT” marking on the collection container. The catheter or cannula with which to carry out the suction operation must be connected to the free end of this tube | |

Before commissioning, check the correct tightness of all elements.

### 9.2 START-UP

For a proper and safe use of the product, proceed as follows:

- Ensure that gas supplies comply with the specifications in this manual.
- Ensure that all components are properly connected

Spencer is available for consultations relating to the use and control activities of the device.
If the device works properly and the conditions stated are met, the device can be considered ready for use; otherwise the device must be immediately put out of service and the manufacturer contacted.

Do not alter or modify the device arbitrarily; modifications may cause unpredictable operation and damage to the patient or rescuers and will also void the warranty, relieving the manufacturer from any liability.

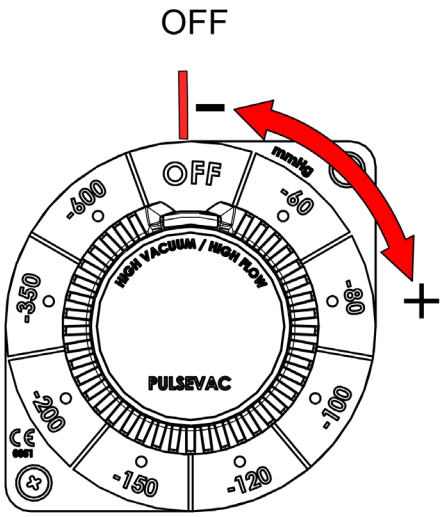
## 10. OPERATING CHARACTERISTICS

### 10.1 DEVICE CHECK

Before the use of the device, it is necessary to check that the canister and the suction probe are properly connected.
Failure to do so, will result in vacuum loss and therefore in reduced performances of the device.

Verify that the canister is properly placed on its support.
Verify that the connection tube coming from the vacuum pump is properly connected to the dedicated hose holder mounted on the wall.
Verify that the filter used to connect the reusable canister is properly connected at both sides.
Check that the connection pipe between the wall hose holder and the vessel is properly connected and guarantees the seal.
Verify that the suction probe at which the suction tube must be connected is applied in a gas tight manner .
If the above conditions are met, the device can be considered ready for use.

### 10.2 ADJUST THE VACUUM LEVEL




The control unit of the device, consists in a rotating knob that has the OFF position at the top, and is used to choose one of the preset vacuum levels.

At the top of the knob, a red indicator shows the selected position.
Each vacuum level has also a led indicator.

The vacuum level is increased rotating the knob clockwise and is decreased rotating it counter clockwise. When a vacuum level is selected, the corresponding led starts to flash until the specific vacuum level is reached. Intermittent lighting means that the corresponding vacuum level has not been reached, fixed light means that the specific vacuum level has been reached.

**If the knob is in OFF position, it is not possible to rotate it counter clockwise**.

Simulating the operation:
- Occlude the suction probe to simulate suction.
- Rotate clockwise the knob and set the value -150 mmHg. The first 5 leds will start to flash. When a vacuum level is reached, the corresponding led stops flashing and the light will become fixed. When all lights are fixed, the vacuum level has been reached and the pump stops working. If vacuum is lost, the pump starts to operate again, to keep the vacuum level set by the operator.
- If a different vacuum level is needed, turn the knob to the desired position.
- When suction is not needed, turn off the device by rotating the knob counter clockwise until the OFF position is reached.

### 10.3 USE

The physician who directs the rescue operation is responsible for the choice of the device to be used and for the clinical assessments needed for the proper use of this device and for the choice of the proper suction parameters.

- Ensure that the canister has been properly connected.
- Set the vacuum level to the desired value
- **Before starting the suction procedure, and prior to each suctioning event, the negative pressure must be checked by occluding the end of the suction tube before attaching it to the suction catheter. The operator must be able to evaluate if the suction level is adequate for the specific application.**
- Start the suction procedure. When the filter comes in contact with body fluids, the vacuum generation at the patient port will cease. **The pump will continue to work until the knob is placed in OFF position.** The canister must always be used in vertical position.
- To avoid the formation of foam, fill the collection container (or the collection bag if Serres canister is used) with 1/3 of water.
- At the end of suction procedure, proceed with cleaning procedures.

## 11. CLEANING AND MAINTENANCE

### 11.1 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.

The described operations must be performed after each use of the device. 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.

- Turn off the device
- Clean the collection container according to the next table and dispose disposable accessories.
- Wipe the canister support and the control unit using a clean damp cloth and detergent.

- The vacuum pump box, considering that it is installed behind the wall and it is not in contact with contaminated agents, doesn't require particular cleaning procedures during normal use. Its cleanliness shall be verified during periodic inspection.
- Do not reuse disposable components because it could result in serious infection risks.

**For cleaning procedures for collection containers, refer to the IFU provided with such accessories.**

### 11.2 ROUTINE MAINTENANCE

Establish a maintenance program and periodic testing routine, identifying an employee responsible for this. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the manufacturer in following paragraphs are checked. All maintenance and periodic servicing activities must be registered and kept together with the servicing reports. These documents have 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.

Routine maintenance of the device must be carried out by operators in possession of specific qualifications, trained and experienced in the use and maintenance of the device. Such training must be recorded and maintained for at least 10 years from the end of life of the product and shall be made available to the competent authorities and / or the Manufacturer upon request.

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

Checks to be carried out before and after each use and at deadline indicated above, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure to clean may cause the risk of cross infections)
- Correct fixation of all nuts, bolts and screws
- No structural part is deformed or compromised
- Visual check of the integrity of pneumatic connection tubes
- Check the functionality of the vacuum source
- Verification of the functionality of the control knob and led lights.

**Every 5 years** the yellow pneumatic connection hose between the vacuum source and the wall hose holder must be replaced.

Use only original or Spencer Italia s.r.l. approved components/replacement parts and/or accessories to carry out any operation without causing alterations or modifications to the device. Otherwise, we decline all responsibility regarding incorrect operation or any damage caused by the device to the patient or the operator, invalidating the warranty and invalidating compliance with EU Regulation 2017/745.

### 11.3 PERIODIC OVERHAUL

**The device must be serviced by the manufacturer or by an authorized centre, every year.**

In the absence of an above-mentioned overhaul, the device must be DECOMMISSIONED, as compliance with Regulation 2017/745/EU will cease and, despite the CE marking, the device will no longer meet the safety requirements guaranteed by the Manufacturer at the time of supply.
Spencer Italia s.r.l. declines any responsibility for incorrect operation or damage caused by use of devices that have not been regularly serviced.

Only overhaul activities carried out by specialised technicians authorised by the Manufacturer are considered valid by Spencer Italia s.r.l.

### 11.4 SPECIAL MAINTENANCE

**Special maintenance can only be carried out by the Manufacturer, who uses internal and external technicians specialised and authorised by the Manufacturer itself.**

Only maintenance activities carried out by specialised technicians authorised by the Manufacturer are considered valid by Spencer Italia s.r.l.

### 11.5 LIFE SPAN

**The device, if used as indicated in the following instruction manual, has a life span of 5 years from the purchase date. Such life span, can be extended for up to another 5 years following the annual revision.**

Overhauls must be carried out by the Manufacturer, who uses internal and external technicians specialised and authorised by the Manufacturer. In the absence of such annual overhauls, the device must be DISPOSED OF ACCORDING TO THE INFORMATION IN PARAGRAPH 16 AND NOTIFICATION MUST BE GIVEN TO THE MANUFACTURER.
The life span may be extended at the sole discretion of the Manufacturer or authorised centre if the safety requirements of the device are still met.
Spencer Italia s.r.l. will accept no responsibility for incorrect operation or damage caused by the use of devices that have not been overhauled by the Manufacturer or authorized centre, or that have exceeded the maximum allowable life span.

## 12. TROUBLESHOOTING TABLE

| PROBLEM | CAUSE | SOLUTION |
|---|---|---|
| | ***Device related issues*** | |
| The device does not turn on | Wrong electrical connection | Check the correct polarity of the connection and that the power source is adequate for the device.<br>If the problem persists, put the device out of service and contact the manufacturer |
| | Improper power supply | |
| | Control unit not connected | Check that the control unit has been properly connected to the vacuum source.<br>If the problem persists, put the device out of service and contact the manufacturer |
| The device does not generate the expected vacuum | Connection tubes not properly connected | Check proper connection of tubes.<br>If the problem persists, put the device out of service and contact the manufacturer |
| | Tubes are contricted | Check that the connection pipes follow a linear path |
| | Damage to the vacuum source | Put the device out of service and contact the manufacturer |
| | ***Issues related to components that are not part of the device*** | |
| No flow/vacuum | Check that the hydrophobic filter of the Serres bag has not been wet.<br>Check that the overflow device of the reusable 1000ml jar has not been activated | Replace the bag or empty the jar following the instructions of the respective manufacturers |
| Breakages in the collection container | Improper use or exceeding the maximum number of sterilization cycles | Replace the canister |

## 13. ACCESSORIES

The accessories allowed to be connected to the device are limited to those identified in the table.

| Device | Charatteristics |
|---|---|
| SC73016 | Sterile suction tube |
| SC73067 | 1000ml reusable canister |
| SC73013 | Semitransparent antibacterial filter PulseVac |
| SC20010 | Antibacterial filter PulseVac |
| SC75015 | 1000ml Serres canister w/bag |
| SC75017 | 1000ml oval container for Serres bags |
| SC75018 | Disposable bags for Serres canister – 36pcs |
| Suction Catheters and cannulas | Compliant with ISO 10993 biocompatibility standards and with conical connector |

## 14. SPARE PARTS

| | |
|---|---|
| RISC027 | VACUUM SOURCE PULSEVAC |
| RISC028 | PULSEVAC CONTROL UNIT WITH CABLE |
| RISC029 | SILICON TUBE ø8X14mm 1m |
| RISC030 | POWER SUPPLY CABLE PULSEVAC |
| RISC031 | CANISTER SUPPORT W/BELT |
| RISC032 | VACUUM TUBE PULSEVAC 2m w/hose holder and clamp |

Contacting the manufacturer or and authorized service center, the product code and serial number of the device in your possession must be provided.

## 15. DISPOSAL

When devices and their accessories are no longer suitable for use, they can be disposed of as normal municipal solid waste if they have not been contaminated by special agents. Otherwise, follow the regulations in force regarding disposal.

**WARNINGS FOR THE CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2012/19/EU WEEE:**

At the end of its life, the product must not be disposed as household waste. It can be taken to special recycling centers provided by local government, or on purchase of a new device of the same type and used for the same functions return it to the dealer. Disposal of the product separately avoids possible negative consequences for the environment and human health resulting from inappropriate disposal and allows recycling of the materials in order to obtain significant savings in energy and resources. The symbol on the label indicates separate collection of electrical and electronic equipment.

**Warning:** Incorrect disposal of electrical and electronic equipment could result in sanctions.