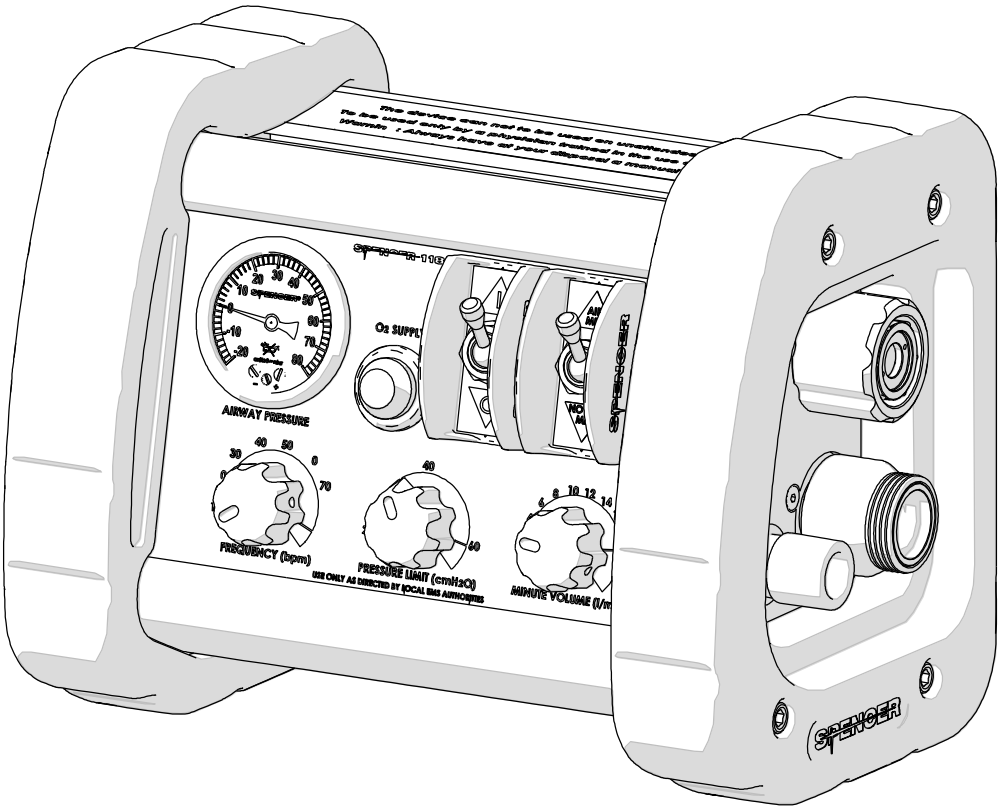
User manual

Spencer 118 NXT
Pneumatic lung ventilator



CE 0123 Class IIb Medical Device, compliant with the Medical device directive 93/42/CE

Warning

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

The Diagrams are inserted only for reference and may vary slightly from the actual device.

Spencer Italia S.r.l. assumes no responsibility for any errors contained herein or for damage, accidents or consequences connected with the supply, performance or use of this manual.

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Quality System EN ISO 9001 – EN ISO 13485

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1. MODELS

The standard following models can undergo change, revision and implementation without any notice.

- Spencer 118 NXT Pneumatic lung ventilator
- Spencer 118 NXT Kompak Pneumatic lung ventilator

The connection standard of the device is the one determined by the customer on the order.

2. INTENDED USE

Spencer 118 is a volumetric breathing support device, pneumatically operated, capable of delivering two different concentrations of oxygen with one medical oxygen supply. The range of voluems and respiratory frequencies allows its use both in adults and children. **It is not allowed the use with newborns.** The device is designed to provide temporary non-invasive ventilation support for patients having a minimal essential breathing capacity. The device is designed for permanent installation inside ambulances. If the device needs to be transported, is necessary to use an adequate transport bag.

3. REFERENCE STANDARD

As Distributor or final User of the products manufactured and/or sold by Spencer Italia S.r.l., it's strictly required to know the law dispositions applied in the Country of destination of the goods, applicable to the supplied devices (including the regulations about technical specifications and/or safety requirements.

REFERENCE	DOCUMENT'S TITLE
EN 794-3	Lung ventilators - Part 3: Specific requirements of the ventilators operated by a source of energy for emergency and transport.

4. INTRODUCTION

4.1 Use of the manual

This manual is intended to provide to the health care operator all the necessary information for its safe and appropriate use as well as adequate maintenance of the device.

***Note**: this Manual is an integral part of the device, therefore it must be kept for the duration of the device and it must accompany the device in case of change of ownership or destination. If the operating instructions received relate to a different product, you must immediately contact the manufacturer before use.*

The Spencer products manuals can be downloaded from the website http://support.spencer.it or they can be requested by contacting the manufacturer. Exceptions are those items whose essentiality for reasonable and predictable use is such as to make it unnecessary to prepare instructions in addition to the following warnings and the directions on the label.

Regardless of the level of experience gained in the past with similar devices, it is recommended to read carefully this manual before installation, use of the product or maintenance.

4.2 Labelling and tracking control of the device

Each device has got an identification label positioned on the device itself and/or on its box, which includes identification data of the manufacturer, the product, the CE mark, the serial number (SN) or lot number (LOT). It must never be removed or covered.

In case of damage or loss, request a duplicate from the manufacturer. Failure to do so will interrupt the validity of the guarantee as the device can no longer be traced.

The Directive 93/42/EEC requires manufacturers and distributors of medical devices to keep track of the device location. If the device is in a different location to the address where it was sent or to where it had been sold, donated, lost, stolen, exported or destroyed, permanently removed from use, or if the device had not been delivered directly from Spencer Italia S.r.l., register your device at http://service.spencer.it or inform Customer Care (see § 4.4).

4.3 SYMBOLS

Symbol	Meaning
	General and/or Specific warnings
	See instructions for use
	Do not lubricate
LOT	Lot number
REF	Product code
SN	Serial number
CE 0123	Product compliant with the Medical device directive 93/42/CE
	Keep in a cool and dry place
	The device must be used before the date indicated on the package (Accessories)
I	ON
O	OFF
	Obligation to read operating instructions

4.4 Warranty and support

Spencer Italia S.r.l. guarantees that the products are without defects for a period of **one year from the date of purchase**.

For any informations regarding the correct interpretation of the instruction manual, the use, maintenance, installation or restore of the product, contact Spencer Customer Care ph. +39 0521 541111, fax +39 0521 541222, e-mail service@spencer.it. In order to facilitate the assistance service, please always indicate the lot number (LOT) or serial number (SN) shown on the label applied on the box or on the device.

Conditions for warranty and assistance can be viewed on http://support.spencer.it.
Note: *Register and store with these instructions: lot (LOT) or serial number (SN) if any, date and place of purchase, date of first use, date of servicing, name of the users and comments.*

To guarantee the traceability of the products and to protect the procedures of maintenance and assistence of Yours devices, Spencer has made available the ASSTEC portal http://service.spencer.it/asstec/login.aspx, which will allow you to view the data of the products owned or on the market, to monitor and update the plans of periodic reviews, to view and manage extraordinary maintenances

5. WARNINGS

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

User training

Note: *despite all the efforts, laboratory testing, post production tests and instruction manuals, the rules can't always reproduce the practical use, therefore the results obtained in the real conditions of use of the product could be notable different.*

The best instructions consist in the continuous practice under the supervision of trained and competent staff.

- Regardless of the level of experience gained in the past with similar devices, it is recommended to read carefully this manual before installation, use of the product or maintenance. If in doubt, contact Spencer Italia S.r.l. to obtain the necessary clarifications.
- The device must be used only by a *trained physician*, having attended specific training for this device and not for similar products, with appropriate clinical knowledge of artificial ventilation in order to correctly set the values available on the device according to the patient's clinical status.
- The suitability of the user to use the product may be attested by the records of training, where the names of those trained, of the trainers, dates and place are indicated. **The register which certifies the eligibility of the operators to use the Spencer device must 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. In the absence of such documentation, sanctions will be applied.**
- Do not allow any untrained person to help during the use of the product, because they could cause damage to themselves or to others.

Note: Spencer Italia S.r.l. is always at your disposal to organise product training.

Installers training

The installer of the device must be able to ensure that all the equipments, systems, containers and connections are compliant to the safety standards and regulations. This requires the knowledge of all the regulations and standards applicable.
If these conditions are not met, the safety of the device and of the operators will be compromised.

Product functionality

The use of the product in any other way than the one described in the User Manual is forbidden.

- Before each use of the device always check its integrity, as specified in the instruction manual. In case of damages/abnormalities that could compromise its safety or functions, it is necessary to immediately remove the device from service and to contact the manufacturer.
- If any failure or malfunctioning of the device is detected, it must be immediately substituted with a similar item, so that the rescue procedures are guaranteed without any interruption.
    - The product 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 product itself; moreover CE certification and product warranty will be considered void.
    - Those who modified or have modified, prepare or have prepared the Spencer Italia S.r.l. medical appliances in such way that they no longer serve the purpose for which they were intended, must satisfy the valid conditions for the first introduction into the market.
    - During the use of the devices you need to position and adjust them in such way that they won't cause any obstructions to the rescuers and/or any other rescue equipment.
    - Make sure that all the necessary precautions are taken in order to avoid the hazards that can arise from the contact with blood or other body fluids, when applicable.
    - Ensure that the fixing system of the device is suitable to keep it fixed in the medical vehicle under all circumstances.
    - **The warranty seals, if present on the product, must not be removed;** in such case, the manufacturer will no longer recognize the warranty of the product and will accept no responsibility in case of malfunctioning or damage caused by the product itself.
    - Avoid contact with sharp objects.
    - Operating temperature: From -10°C to +40°C
    - Atmospheric pressure: From 70 to 110 kPa
    - Relative humidity: 15% – 95%

Storage

- The device should not be exposed or be in contact with any source of combustion or inflammable agents. It must be stored in a dry and cool place, repaired from sun and light.
- Do not store the product underneath any object, heavy or not, which could cause structural damage.
- Store and transport the device in its original packaging. Failure to do so makes the warranty void.
- Storage temperature: from -30°C to +70°C

Maintenance/Cleaning

Spencer Italia S.r.l. declines any liability for any damage, direct or indirect, which is a result of an improper use of the device and its replacement parts and/or of any repairs made by someone other than the Manufacturer, which employs authorized internal and external trained technicians; in this case the warranty is void.

- During all the operations of checking, maintenance and cleaning procedures, the operators must always wear adequate protection devices, such as gloves, glasses, etc.
- If required from the Manufacturer in the User Manual, it must be established a plan of maintenance, periodic testing and extension of the average lifetime, identifying an employee responsible for overseeing. He must ensure the basic requirements foreseen by the Manufacturer in the User's Manual.
- **The frequency of inspections is determined by factors such as legal requirements, type of use, frequency of use, environmental conditions during use and storage.**
- Repairs must necessarily be carried out by an authorized Spencer Italia S.r.l. service centre, which in using original spare parts will provide a quality repair service in strict accordance with the technical specifications given by the manufacturer. Spencer Italia S.r.l. declines any liability for any damage, direct or indirect, which is a result of an improper use of the replacement parts of the device and/or of any repairs made by unauthorized subjects.
- Use only original components/spare parts and/or original accessories or approved by Spencer Italia S.r.l., in order to carry out any operations without causing alterations or modifications to the device.
- All the maintenance and revision activities must be recorded and documented with the corresponding report of technical assistance. The documentation must be maintained for at least 10 years from the end of life of the product, and must be made available to the competent authorities and/or the Manufacturer if requested.
- The cleaning, scheduled for reusable products, must be performed in accordance to the directions provided by the Manufacturer in the User Manual, in order to avoid the risk of cross-infections due to the presence of secretions and/or residuals.
- The device and all of its components, if washed, should be allowed to dry completely before storing.

Regulatory requirements

As Distributor or final User or the products manufactured or sold by Spencer Italia S.r.l., it is strictly required to have a basic knowledge of any legal requirements applied in the country of destination of the goods, applicable to the devices contained in the supply (including laws regarding technical specifications and/or safety requirements). It is also required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.

- Promptly notify Spencer Italia S.r.l. (already during the first product enquiry) when requesting details regarding any revisions to be made by the Manufacturer in order to guarantee the conformity of the products to the territory's legal specifications (including those required by different regulations and/or regulatory provisions).
- Act, with all due care and diligence, and contribute to ensure the conformity to the general safety requirements of all the devices marketed in the territory, providing to the final users all the necessary informations to carry out periodical checks on the devices, exactly as written in the User Manual.
- **Actively contribute during safety check of the product sold,** by communicating any relevant information regarding the risks of the product to the Manufacturer and to the competent authorities, so that necessary actions can be promptly taken.
- The Distributor or final User is aware that in the event of any failure to conform to the above mentioned requirements will be deemed fully responsible for any damage that might occur. Spencer Italia S.r.l. disclaims any responsibility and/or liability for your non-compliance with the present regulatory provisions.

General warnings for medical devices

The user must read carefully not only the general warnings, but also those listed below.

- It is not foreseen that the use of the device is prolonged beyond the time necessary for the first responders to complete their operations and to complete the subsequent stages of transport to the nearest rescue point.
- During the use of the device the assistance of qualified staff must be guaranteed, and at least one physician trained to the use of the device must be present.
- Follow the procedures and protocols approved by your internal organization.
- If disposable accessories are used, use only once and for only one patient. Do not wash or sterilize after use. Reuse may cause cross-infection. Some symbols contained in this manual refers to the standard accessories included in the purchased device.
- The activities of disinfection (and sterilization of the accessories if required) should be carried out in accordance with the parameters given in the validated cycle, as specified in the technical standards. Sterilization could reduce the lifetime of the devices.
- Do not use accessories after the expiration date indicated on the package, if present.
- 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 concerning Medical Devices, we remind both public and private operators, that if in the exercise of their activity they detect an accident involving a medical product, they are required to notify the Ministry of Health, under the terms and in the manner established by the relative ministerial decrees and also to the manufacturer. Health care operators whether public or private are required to communicate to the manufacturer any other inconvenience that may allow the adoption of measures that can ensure the protection and health of patients and users.

6. SPECIFIC WARNINGS

- The device is intended to be used on medical vehicles and not for home therapy.
- **Do not use the device with patients of age between 0 and 18 months, and with patients with not drained pneumothorax.**
- Do not use the device on patients with respiratory arrest or that don't have minimal essential breathing capacity.
- The device is intended for NIV. It is not suitable for procedures that requires intubation.
- Do not use if the device presents any kind of damage or poor cleaning state.
- The proper operation for the lung ventilator is closely linked to the suitability of the pneumatic power source. Is therefore essential to check that the pneumatic supplies comply with the requirements described in this manual as well as to specific guidelines and standards for such devices.
- **Ensure that the medical gas supply is free from condensation, residual materials and/or substances which may compromise the proper operation of the device and the efficacy of the therapy or that could contaminate the patient.**
- The device must be protected from bumps, falls and spillage of liquids that could damage the device.
- The device must be used by a physician trained in the use of this product.
- The user must not have impairments that prevent proper reading and interpretation of informations displayed on the device and prevent proper operation of controls.
- Do not wash or clean the device with water jets or pressurized air.
- Do not use drying machines.
- Condensation, water, ice and dust accumulation can affect the correct functioning of the device, making it dangerous for the patient and for the operators.
- Before and after each use, check the status of the enclosures and of the fixing system of the device; if altered or yielding is noticed, is necessary to restore its security status before using the device. Otherwise we assume no responsibility about proper functioning or any damage caused by the device.
- Regularly check the status of pneumatic connections.
- If any failure or incorrect functioning of the device is detected, the ventilation must be immediately restored with a similar device or a manual one in order to ensure the life support functions without interruption.
- Before each use of the device the perfect operating state of the device must be checked as specified in the User manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- When the device is being used, the assistance of qualified staff must be ensured.
- The device must always be accompanied by a replacement unit and/or by a manual ventilation system in order to ensure the possibility to intervene on the patient in any case. The use of Spencer manual resuscitators is suggested.
- Do not leave the patient without the assistance of at least one doctor or operator with clinical skills on artificial ventilation when the device is used.
- The device is equipped with warranty seals. If removed, the manufacturer will no longer recognize the product warranty and accepts no responsibility for improper operation or damage caused by the device.
- If the device comes with disposable accessories, these should be used of only one patient. Cannot be washed, sterilized or re-sterilized after use.
- If the device comes with accessories with limited lifespan, do not use them after the expiration date.
- The device should 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 the 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.
- **The device must be used in a ventilated environment.**
- The utilization of the ventilator with supply sources and environmental conditions different from the indicated ones compromises the safety of the operations and of the device itself.
- Do not lubricate any part of the device. It's not required by any kind of maintenance and could cause fire hazard.
- The artificial ventilation can have side effects. In order to identify the hazards associated with the use of the device, related to the clinical conditions of the patient, is essential the presence of an expert doctor who can evaluate the actual benefits provided by the artificial ventilation and who is able to determine if the ventilator can be used. Side effects are only partially limited by the time of use of the device, intended for emergency and not for prolonged therapy.
- For the use of the ventilator, a specialized doctor must be present. The doctor will be able to determine if the technical specifications of the device makes it suitable to be used on a specific patient and will be the sole responsible for the definition and setting of the ventilation parameters.
- Do not use the device in presence of inflammable substances and anesthetics.
- Do not use the device if the condition of the paragraph 9 are not met.
- Do not use the device if it has not been subjected to scheduled maintenance or maintenance required by a normal use.
- Use only accessories approved by the manufacturer.
- The device is intended for NIV and, as such, is generally not suitable in the following cases:

Respiratory arrest or severe cardiorespiratory impairment – Uncooperative patients (coma, shock, altered state of consciousness) – Excessive secretions – copious bronchial secretions and/or need of frequent suction – Vomiting – Inability to protect upper airways – Obstruction of upper airways – Cranio-facial trauma or burns – Recent facial, upper gastrointestinal tract or upper airways surgery – anatomic lesions of the upper airways - Life-threatening hypoxemia – Hemodynamic instability – Sever comorbidities – Undrained PNX – Sever obesity

- NIV may have complications related to the interface or administred gases, including: Discomfort, facial erythema, claustrophobia, inhalation of gastric regurgitation, nasal congestion, dry mouth, eye irritation, barotrauma, intolerance and agitation, hypoxia due to mask removal.

6.1 Requirements of operators

Spencer 118, is a device intended for professional use only. Each operator must be trained in their use and maintenance of good operating conditions. Do not allow untrained people to assist in the use of the product, as this may cause injury to themselves or others.

Installers and operators must know all the standards applicable to the devices, accessories and systems connected to the pulmonary ventilator.

Operators must be able to assess the integrity of the connections. They must also be able to evaluate any anomalies of the supply systems communicating the problem to the responsible figures, interrupting the use of the devices connected to it.

The abilities of all operators must be considered before determining their role in the employment of the device.

The device can be used only by specialized staff which will be able to determine if the technical specifications of the device make it suitable to be used on a specific patient and will be the sole responsible for the definition and setting of the ventilation parameters.

7. RESIDUAL RISK

The residual risks listed below have been identified exclusively in reference to the intended use of the device.

- Installation carried out by untrained personnel can lead to detachment of medical gas pressurized tubes, resulting in damage to people or impossibility to carry out rescue operations.
- Installation carried out by untrained personnel, could result in inadequate fastening of the device inside the ambulance, with consequent risks related to its instability or mobility.
- The connection to a gas supply having impurities or traces of condensate can compromise the good functioning of the device, altering its functional characteristics and causing harm to patients.
- Failure to check the compliance of the pneumatic supply, may result in unattended therapy interruption.
- The use in environmental conditions different from those specified in this manual, can damage the sealing elements resulting in leakage of gas, deviations from the set flow values or condensation.
- The use in presence of flammable and/or anesthetic gas may cause fire risks
- A prolonged use without adequate humidification downstream the device, can cause dryness of the patient airways.
- The use of Air Mix mode in polluted atmosphere can result in serious damage to the patient.
- The use of adult breathing circuits on pediatric patients may cause barotrauma.
- Wrong choice of the mask size, can lead to oxygen leakage decreasing the effectiveness of the ventilation therapy or leading to improper operation of alarms.
- The artificial ventilation can have side effects. In order to identify the hazards associated with the use of the device related to the clinical conditions of the patient, its essential the presence of an expert doctor who can evaluate the actual benefits provided by the artificial ventilation and able to determine if the ventilator can be used. **The doctor will be able to assess the type and cause of respiratory insufficiency, ensuring adequate therapy** evaluating the actual need and possibility to use the ventilator setting the proper values in relation to the clinical condition of the patient. The absence of such figure can seriously compromise the patient safety because of inadequate treatment, ineffective or due to an improper use of the device.
- Side effects are only partially limited by the time of use of the device, which should never exceed the time for the transport of the patient on the ambulance. Risks arising from prolonged use, are closely linked to the side effects of NIV.
- The reuse of unsterilized patient circuits, involves risks of infection for patients and operators.

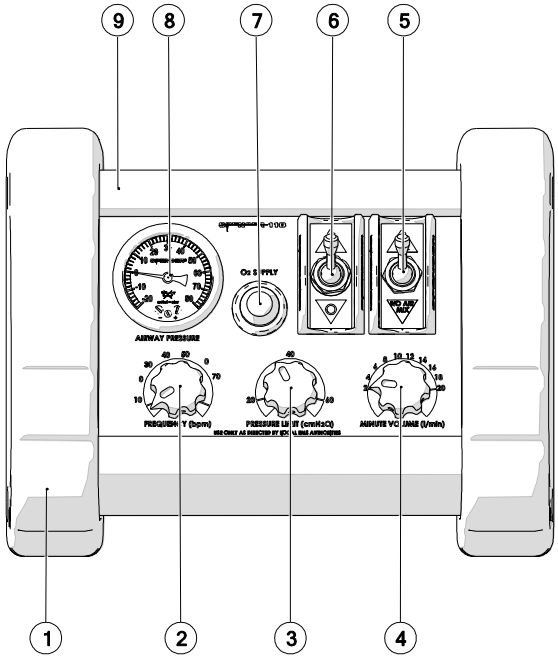
8. TECHNICAL DATA AND COMPONENTS

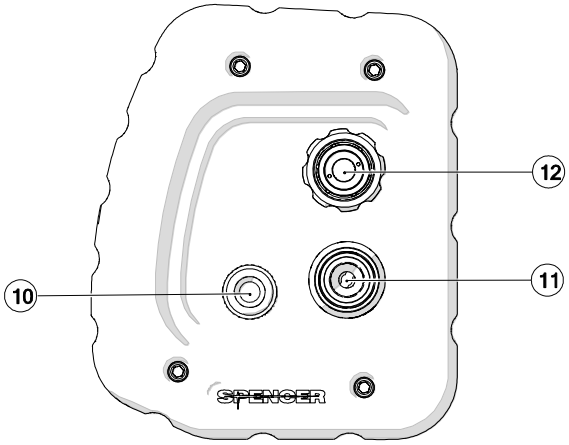
Note: Spencer Italia S.r.l. reserves the right to make changes to specifications without prior notice.

8.1 Technical data

DIMENSIONAL DETAILS			
Width	270 mm		
Height	210 mm		
Depth	177 mm		
Weight	3,84 ± 0,1 kg		
Patient circuit weight	242 g		
Patient circuit volume	400 ± 20ml		
Pneumatic supply			
Gas supply	Medical oxygen		
Operating pressure	From 280 to 600 kPa		
Maximum flow rate required	140 l/min		
VENTILATION			
Modality	VC-CMV (CMV)		
Volume/minute	From 2 to 20 L/min		
Ventilation frequency (***F***)	From 10 to 70 BpM		
Tidal Volume	$VT = \frac{\frac{Volume}{minute}}{F}$		
FiO_2	80% (AIR MIX) o 100% (NO AIR MIX)		
I/E Ratio	1:2.0 ± 0,3 at 10bpm 1:1.5 ± 0,3 at 70bpm Linearly variable between the given parameters		
Respiratory resistances	Valve	Filter	Breathing tube
	2,5 cmH_2O exp. 1,73 cmH_2O insp at 50 l/min	2,5 cmH_2O at 60l/min	0,12 cmH_2O at 30 l/min 0,51 cmH_2O at 60 l/min
Breathing tube compliance	Less than 2% of volume		
High pressure alarm	60 mbar ± 5%		
MANOVACUOMETER			
Measuring range	From -20 to +80 mbar		
Precision class	1,6 (maximum error ± 1,3 mbar)		
MAXIMUM DEVIATION FROM SETTINGS			
Volume minute	± 15%		
Frequency	± 1 BpM		
Pressure limit	± 5 mbar		
Alarms			
Acoustic	High pressure		
Acoustic level	80 ± 5 db		
Classifications			
Classification according to dir. 93/42/CE	IIb		

8.2 Components





N°	Description	Material	N°	Description	Material
1	Side protections	PE	7	Bi-coloured indicator for oxygen supply	POM, Acrylic glass
2	Frequency adjustment knob	Al	8	Manovacuometer	Copper alloy/Steel/Al
3	P_{MAX} Adjustment knob	Al	9	Main Body	Al
4	Flow adjustment knob	Al	10	Breathing circuit connector	Al
5	AIR MIX/NO AIR MIX selection lever	Steel	11	Gas supply connector	Brass, nickeled brass, ABS
6	ON/OFF switch	Steel	12	Air intake	Al/PE

The device comes with the following accessories not shown in this manual:

- **Patient circuit**

It consists of a corrugated tube, face mask, non-rebreathing valve, straight fit and bacterial filter. Patient circuits or their components approved to be used with the pulmonary ventilator are those listed in paragraph 15.

- **Oxygen connection tube**

Allows the connection of the device to the oxygen supply.
Contains DINP phtalates

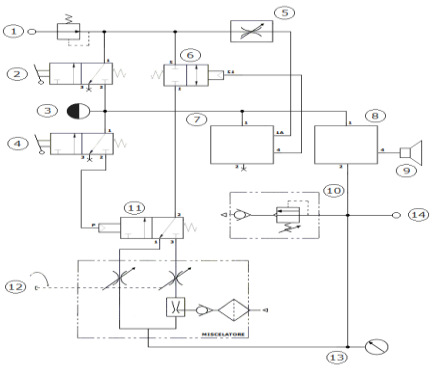
- Devices intended for transport are equipped with a suitable bag and include standard accessories stored in dedicated compartments inside the systems.

Those accessories are:
- 2l Oxygen tank
- Pressure reducer with the connection standard specified in the order.
- Helicoidal mouth opener
- Tongue forceps
- Guedel cannulas

8.3 Pneumatic diagram

The lung ventilator 118, is equipped with an internal pneumatic circuit complying with the following diagram:

1. High pressure source
2. ON/OFF Switch
3. Gas supply pressure status
4. AIR/MIX Switch
5. Frequency regulator
6. Patient circuit control valve
7. Alarm circuit
8. Pneumatic oscillator
9. Acoustic alarm
10. Overpressure valve
11. AIR/MIX Command valve
12. Volume Minute mixer
13. Manovacuometer
14. Medical gas output – patient circuit



This diagram is provided only to illustrate the operation of the device. It is not allowed to intervene in any way on it as well as on the electronic circuit. If opening of the case of the device or any other type of unauthorized modification will be found, the warranty would be voided and Spencer Italia will not have any liability related to the functionality and use of the product. The pneumatic circuit can be modified or implemented without prior notice.

9. INSTALLATION AND START-UP

9.1 Installation

The installation of the device is a critical step to ensure a proper operation. When the product is recieved, verify that:

- The packaging is intact and has no signs of impacts, falls and isn't wet.
- All the items in the accompanying list are present
- The device does not show any kind of damage
- Ensure that the vehicle in which you want to install the device, is manufactured in compliance with EN 1789.

If the conditions above are met, is possible to install the device verifying that:

- The installation floor is leveled 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 medical gas supply system has been regularly serviced or, in case of initial startup, the periodic maintenance has been programmed.
- Fittings, pipes and all means of connection used in the system, are built according to the specific applicable standards.
- Verify that purchased tubes and fittings respect the same standard requested for the device.
- The positioning of the device does not cause any type of obstruction inside the medical vehicle.
- The pressure and flow delivered from the medical gas supply system, have the characteristics specified in this manual
- The device must be installed using the dedicated surfaces on the lower side of the main body. Other fixation devices are available upon request. Any other type of installation, precludes the safety and functionality of the device.

The device must be connected to a source of medical gas having the following characteristics:

Medical gas supply	
Pression	From 280 to 600 kPa
Flow	> 140 l/min
Connection standard (If not otherwise specified on accompanying documents)	UNI (Available standards BS, DIN, AFNOR)

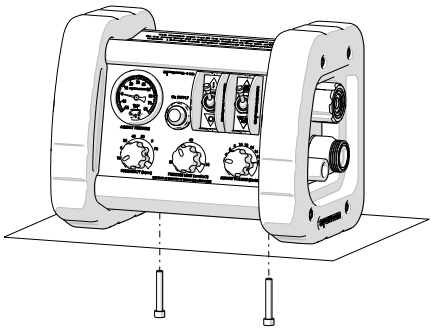
After installation and pneumatic connections, is necessary to check the proper functioning of the device.

The installation of the device must always allow the optimal view of the control panel and must ensure easy access to the connections.

On the bottom of the device, there are two threaded pads for installation on a flat floor.

- Drill two holes on the surface for the screws.
- Choose screws of appropriate length according to the installation surface.
- Tighten the screws until a safe fix is reached.
- Make sure the screws are fully seated. If they are not perfectly coupled with the surfaces, is necessary to choose shorter ones or, if the distance between the screw and the surface is reduced, apply washers.

If you have a **NXT MAX fastener**, carry out the installation as required in its user manual.



9.2 Start-Up

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

- Ensure that the gas supply complies with the specifications in this manual. Is necessary to ensure that oxygen tanks and pressure regulators comply with appropriate regulations and directives that can be applied to those devices. Their proper operation should always be checked before each use.
    - Always check the residual content of the oxygen bottles.
    - Connect the patient circuit and all its components to the unit
    - Check that the manovacuometer is on “zero” position.
- Check that the pneumatic indicator on the front panel is green colored. If red color is displayed instead green, this means that the gas input pressure is too low. Carefully check the oxygen supply.
- Turn on the device using the ON/OFF switch
- the device automatically starts the ventilation in accordance with the previously set parameters. If this does not happen, refer to the table “TROUBLESHOOTING”.
- Adjust the breathing frequency.
- Adjust the minute volume.

Carry out functional test of the overpressure valve in this way:
Close with the palm of one hand the patient outlet and turn the pressure limiting knob. Verify that the value indicated on the gauge is the same set with the knob. The checks must be done on all the adjustment scale.
If the values are not the same or outside the tolerances, put the device out of service and contact the manufacturer or service center.

Carry out functional test of the alarm systems as described in paragraph 12.2.2

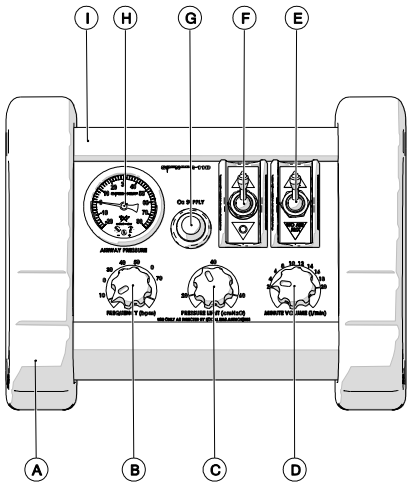
Once the tests are carried out, is necessary to:

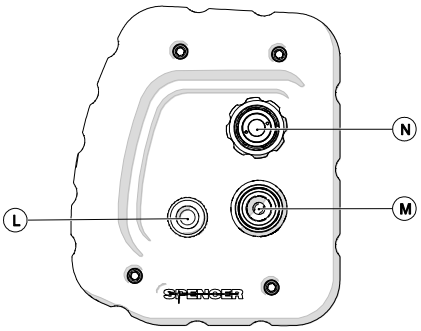
- Turn off the device
- Break off the medical gas supply

If the device is working properly and the conditions above are met, it can be considered ready for use; otherwise put the device out of service and contact the manufacturer.
The patient circuits to be used in place of the one provided, are to be chosen from those approved by the manufacturer and listed in paragraph 14.

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. FUNCTIONAL DETAILS





Element	Description	Function
A	Side protections	Provide additional protection to the primary enclosure increasing the stability of the device.
B	Frequency adjustment knob	Allows to set the breathing acts per minute
C	P_{MAX} Adjustment knob	Allows to set the maximum pressure limit that can be reached during ventilation
D	Flow adjustment knob	Allows to set the delivered volume minute
E	AIR MIX/NO AIR MIX selector	Allows to choose whether to use the medical gas delivered by the medical gas supply system at 100% (NO AIR MIX) or at 80% (AIR MIX), mixing it with air taken from the environment in which is placed the device.
F	ON/OFF switch	Identified by symbols “I” and “O”, allows to turn on and off the device
G	Bi-Colored indicator for gas supply	It is a visual indicator which allows to identify the low pressure gas supply. It shows green color if the pressure is within the allowed range, and turns red if the supply pressure is too low.
H	Manovacuometer	Shows the pressure inside the patient circuit

I	Main body	Main envelope of the device
L	Patient circuit connector	Output at which the patient circuit complete of overpressure valve must be connected .
M	Medical gas input	Input at which must be applied the tube connected to the medical gas supply system. The standard used is UNI. This connection is marked O_2 SUPPLY
N	Air intake	This component is identified by the words EMERGENCY AIR INTAKE, and allows spontaneous breathing of the patient in the event of device failure, by drawing air from the environment

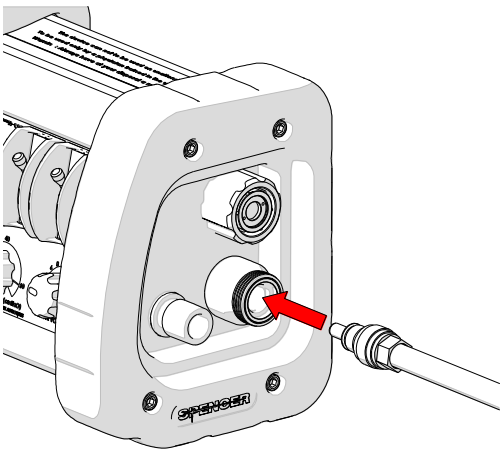
For their use, the pulmonary ventilators require fundamental accessories that make up the patient circuit, which includes in the assembly order the Mask, Patient valve, straight fit, antibacterial filter, corrugated tube.
Spencer 118 includes:

Component	Description
Straight fit 22/15	Allows the connection between the filter and the patient valve
Corrugated tube	Canalizes the medical gas flow and connects the devices of the patient circuit. It is directly connected to the medical gas output placed on the ventilator
Patient valve	Equipped with overpressure and non-rebreathing valves, allows the connection between the mask and the straight fit. It must be chosen according to the patient to be treated (Adult or Pediatric)
Filter	Antibacterial filter placed between the straight fit and the corrugated tube
Face mask	Is the main interface between the device and the patient

***Supplied accessories can be modified without notice**

11. INSTRUCTIONS FOR USE

11.1 Connection to the pneumatic supply



Connect the pneumatic supply hose to the socket
placed on the pressure reducer installed on the oxygen tank. Insert then the probe inside the socket on the connections side of the lung ventilator pressing until it clicks confirming the proper connection.
To verify the integrity of the electrical connection, slightly pull the connector verifying that no disconnection happens.
For the pneumatic supply, slightly pull the probe doing a little rotation at the same time.
Connect the breathing tube to the output marked with “PATIENT CIRUIT” on the connections side of the lung ventilator. The tube must be inserted for about 2,5 cm. If the insertion is difficult, the tube can be slightly rotated during insertion making the operation easier.
The breathing tube must not rotate easily and freely. If this happens, it is an obvious sign of damage to the hose or of its incompatibility with the device.

In these conditions the device is ready for use.
To disconnect the device from the pneumatic supply, push the outer plastic part of the socket in axial direction while pulling out the probe.

11.2 Turn on the device

Turn on the device operating the dedicated lever bringing it in the position indicated by the symbol “**I**”.
If the pneumatic supply has enough pressure to allow a proper operation of the device, the indicator on the frontal panel will show green color..
The device will start automatically the ventilation according the set parameters.
In case of failure, or if the indicator shows red color, refer to the section “TROUBLESHOOTING”.

11.3 Setting breathing parameters

On the frontal panel there are 3 adjustment knobs. Breathing parameters must be adjusted before applying the mask to the patient. During these adjustments, the physician using the device must consider the patient’s weight, the Tidal Volume required by the patient and its clinical conditions.

Volume minute adjustment
The Volume minute is the volume of gas delivered to the patient in a minute. It differs from the delivered volume for each breath (or Tidal Volume) as this is closely related to the breathing frequency according to the relation $VT = \frac{\frac{Volume}{minute}}{F}$.
The device allows setting between 2 and 20 L/min

Breathing frequency adjustment
Rotating the frequency adjustment knob, is possible to set the number of breaths per minute.
The frequency settings influence the *VT* according to the already described relation.
The device allows adjustment in the range between 10 and 70 breaths/min (bpm).

Pressure limit adjustment

Through this setting, is possible to limit the maximum pressure in the breathing circuit to the desired value. **If the pressure limit is exceeded, the volume minute is no longer guaranteed.**

The device allow settings between 20 and 60mbar.

The high pressure alarm is activated only when the pressure inside the patient circuit exceeds 60mbar.

11.4 Ventilation mode

Modalità controllata (VC-CMV)

The controlled ventilation mode starts automatically when the device is turned on if the gas supply is adequate. This ventilation mode consists in the delivery of the medical gas to the patient according to the parameters set with the adjustment knobs.

The I:E ratio (duration of the inspiratory and expiratory phases) is linked to the frequency value you set and varies linearly between the values of 1:2 and 1:1.5 respectively at the minimum and maximum frequency values.

Spencer 118 has not other ventilation modes.

Air Mix/No Air Mix selection

The lever placed on the front panel, allow to choose between two available FiO_2 levels.

If in NO AIR MIX mode, the ventilator delivers only the medical gas coming from the main medical gas supply to which the device is connected. If the supply system delivers oxygen, the ventilator will deliver to the patient an oxygen concentration of 100%.

Selecting the AIR MIX mode, the device mixes the gas coming from the gas supply with the air of the environment where the device is used. In this case, if the main gas supply deliver oxygen, the concentration of this gas administered to the patient will be of 80%.

It is inappropriate to use the Air Mix mode in case of polluted environment. The device has a filter for incoming air subjected to periodic replacement as specified in paragraph 12

11.5 Usage

The physician who directs 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 ventilation parameters.

Patient circuits used for the ventilation must be chosen among those approved by the manufacturer. For ventilation of pediatric patients, a pediatric patient valve must be used.

The residual pressure of the medical gas supply must be regularly checked to ensure enough autonomy. The achievement of the pressure of the residual valve of the oxygen bottle, would result in the shutdown of the device and in the activation of the red indicator placed on the frontal panel.

The device is equipped with an high pressure alarm intended to limit risks related to improper adjustments.

This alarm is activated when the pressure inside the patient circuit exceeds 60mbar and is automatically deactivated when the alarm condition no longer exists.

The manovacuometer on the frontal panel, allows a constant monitoring of the pressure inside the patient circuit.

In standard conditions it is suggested to remove any implants, evaluate the need of bronchoaspiration, hyperextend the patient's head and, to ensure that the airways are clear, position the face mask over the mouth and nose checking the adherence of the soft part of the mask on the patient's face, in order to obtain a sealed system. It is important to verify that the mask is suitable for the patient; in the early stages of the ventilation it is suggested to force the adhesion of the mask to the patient's face.

The adjustment method of the volume minute knob (by steps), prevents changes in the set parameters due to accidental contacts.

Resistance of the airways due to obstructions or external cardiac massage does not cause a variation of the respiratory volume and frequency. In case of reduction of the compliance, the ventilator will react with a rise of respiratory pressure at a constant volume.

During ventilation, constantly monitor the patient's physiological response in order to verify if the set parameters are correct or to ensure absence of complications.

Note:

The medical gas flow is not influenced by pressure. The ventilator does not monitor the oxygen concentration (mechanical mixing). Unless otherwise specified the parameters are expressed in ATPD (Ambient, Temperature and Pressure Dry).

At the end of service, turn off the device by putting the lever on the "**O**" position, shut down the pneumatic supply and proceed with the necessary maintenance activities.

11.6 Alarms and information signals

Each visual, acoustic or visual/acoustic signal is generated by conditions requiring attention and intervention by the operator.

The device is equipped with the following alarms

Physiological alarms	
HIGH PRESSURE	
Alarm specification	Continuous acoustic signal pneumatically generated
Meaning of the alarm	The pressure limit inside the patient circuit has been exceeded. The alarm is activated when the pressure of 60mbar is exceeded
Possible causes of activation	1 – The minute volume set is too high 2 – The patient circuit tube is crushed or obstructed 3 – Resistance of patient's airways cause the activation of the alarm
Action to take	1 – decrease the volume minute 2 – Free the patient tube and restore safety conditions 3 – Check the ventilation parameters and the clinical status of the patient. It is necessary to carry out in-depth assessments to verify the need of intubation and therefore the ventilation by means of other instruments.

Technical alarms	
PNEUMATIC SUPPLY (O_2 SUPPLY)	
Alarm specification	Continuous visual pneumatically activated
Reason of activation	The pressure of the pneumatic supply is low
Possible causes of activation	1 – The gas supply doesn't have adequate performances for this device 2 – Oxygen tanks are empty
Action to take	1 – Put the device out of service and verify the performances of the gas supply. 2 – Verify the remaining pressure of the oxygen tanks considering the pressure of the residual valve.

Here is shown a table for general guidelines about autonomy of bottles of various capacities.

Autonomy expressed in minutes for a tank loaded at 200bar										
Tank capacity (liters)	Selected flow (l/min)									
	2	4	6	8	10	12	14	16	18	20
2	200	100	67	50	40	33	29	25	22	20
3	300	150	100	75	60	50	43	38	33	30
5	500	250	167	125	100	83	71	63	56	50
7	700	350	233	175	140	117	100	88	78	70
10	1000	500	333	250	200	167	143	125	111	100
14	1400	700	467	350	280	233	200	175	156	140

12. CLEANING AND MAINTENANCE

12.1 Cleaning

La mancata esecuzione delle operazioni di pulizia può comportare il rischio di infezioni crociate dovute alla presenza di secreti e/o residui.

Durante tutte le operazioni di controllo e igienizzazione l'operatore deve indossare adeguati dispositivi di protezione individuali, quali guanti, occhiali etc.

- The described operations must be performed after each use of Spencer 118.
- Turn off the device and disconnect it from the gas supply
- La pulizia esterna dell'apparecchio può essere effettuata con l'ausilio di appositi disinfettanti per superfici come indicato in tabella:

USABLE PRODUCTS	NOT USABLE PRODUCTS
Disinfectants with aldehydes	Compounds that release halogens
Disinfectants with alcohol	Strong organic acids
Quaternary ammonic compounds	Compounds that release oxygen
	Trichloroethylene

- Be careful to ensure that no kind of solution enters inside the oxygen socket..
- If is used a disposable patient circuit, replace it.
- If is used a reusable patient circuit, disassemble every part and sterilize according to a validated procedure.
- Similarly, replace or sterilize the mask.
- After confirming the ventilator and all accessories are completely dry, is possible to reconnect the device to the power supply.

The use of high pressure water is prohibited, because it should penetrate into the device causing risks of corrosion of components and risks of electric leakage and short circuits. During every cleaning procedure, check that were not used any kind of lubricants.

12.2 Ordinary 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 inspected.
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.

To guarantee the traceability of the products and to protect the procedures of maintenance and assistence of Yours devices, Spencer has made available the ASSTEC portal http://service.spencer.it/asstec/login.aspx, which will allow you to view the data of the products owned or on the market, to monitor and update the plans of periodic reviews, to view and manage extraordinary maintenances.

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.

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 of cleaning may cause the risk of cross infections)
- Correct fixation of all nuts, bolts and screws
- No structural part is deformed or compromised
- Proper operation of the pressure limiting adjustment controls. With the device turned on, occlude the patient output and verify that the manovacuometer shows the pressure value set within the tolerances described in the technical data. Verify proper functionality of the frequency knob setting a value and measuring the time between two mandatory ventilations. The time in seconds between two ventilations is equal to 60/Frequency.

The pneumatic connection pipes must be replaced every two years

12.2.1 Alarm functionality test and pressure indicator test

The functionality of the high pressure alarm and the functionality of the gas supply indicator shall be checked at least once a month to ensure that the devices is suitable for use.

High pressure alarm test :
Connect the device to the pneumatic supply.
Set the minute volume at the lower value
Set the pressure limit at 60 mbar
Turn on the device
Close with one hand the port used to connect the breathing tube making sure it is completely obstructed.
Gradually increase the volume minute until the alarm is activated. When the alarm starts the pointer of the manovacuometer should show a pressure level of 60 mbar. If the alarm is regularly activated the test is successful.

Pneumatic supply alarm Test:
Connect the device to the pneumatic supply.
Check that the indicator is red colored.
Open the oxygen bottles and turn on the device.
Check that the indicator color has changed from red to green.
If the change in color has occurred, the test can be considered successful.

In the event of prolonged inactivity periods or before transports, do the following:
- Turn off the device and disconnect it from the gas supply.

For prolonged inactivity, in addition to the recommendations listed above, the device must be stored following other precautions about the place, time and modality of storage:
- Store the device in a closed place.
- Protect it from shocks and stresses
- Proteggerlo dall'umidità e da escursioni termiche elevate.
- Avoid contact with corrosive substances.

The procedures listed below shall be carried out and checked before each use of the device.

	To check	Required result
RESPIRATORY SYSTEM	• Corrugated Tube • Non-rebreathing valve • PEEP valve (if present) • Face mask • Ventilation test • Disposable filter • Connection	• All components have to be in good conditions and correctly connected • The device or its components must be correctly cleaned or replaced.
PNEUMATIC POWER SUPPLY	• Pressure reducer and oxygen tank. • Connection between the oxygen tube and the device input • Presence of unified plug for connection to the gas supply or correct connection to the pressure reducer of the tank	• The pressure regulator must be subjected to periodic maintenance and the oxygen tanks must have enough autonomy to ensure the proper operation of the device. • The connection to the output of the pressure reducer is safe • There are no active alarms

In the event of failure of the pneumatic supply, is necessary to switch to another ventilation equipment.

Always check that at least one alternative artificial ventilation equipment, so the rescue procedures can be carried out also if any failure occurs.
The proper operation of the pneumatic supplies must always be guaranteed. Carefully follow the instructions and carry out the maintenance required by manufacturers of such devices.

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage.

Please note that you must do the cleaning as described in this manual and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the improper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance and will void the warranty and the compliance to the Medical Device Directive 93/42/CEE.

Use only accessories/original spare parts approved by Spencer Italia S.r.l., otherwise we will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the manufacturer or by one of the manufacturer's authorised service centres. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

12.3 Periodic maintenance

Il dispositivo deve essere revisionato ogni anno dal Fabbricante, che si avvale di tecnici interni ed esterni specializzati ed autorizzati dal Fabbricante stesso.

In mancanza della suddetta revisione, decade la conformità alla Direttiva 93/42/CE Dispostivi Medici e, pertanto, nonostante la marcatura CE, il Dispositivo potrebbe non rispondere più ai requisiti di sicurezza garantiti dal Fabbricante all'atto della fornitura.
Spencer Italia srl declina ogni responsabilità sul funzionamento non corretto o su eventuali danni provocati dall'utilizzo di dispositivi non revisionati regolarmente.
Si intendono validate da Spencer Italia S.r.l. solo le attività di revisione svolte da tecnici specializzati ed autorizzati dal Fabbricante.

12.4 Manutenzione STRAORDINARIA

The device must be serviced by the manufacturer or by an authorised centre every year.

If the correct revision is not carried out, the CE branding will no longer be considered valid as the product will no longer be compliant with the 93/42/CE Directive for Medical Devices and consequently it is no longer compliant with the safety standards declared by the manufacturer at time of purchase.
Spencer Italia S.r.l. will take no responsibility 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

12.5 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.

The life span of the device is of 5 years from the date of purchase and can be extended for up to another 5 years following the annual revision.
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 ACCORDING TO THE PROCEDURES SPECIFIED IN PARAGRAPH 16 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 centre, or of any device for which the life span is expired

13. TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Gas Supply indicator is red colored	The device is not turned on	The indicator shows the gas supply status only if it is turned on
	The lung ventilator is not connected to a pressurized gas supply	Connect the device to a pressurized medical gas supply
	The oxygen content inside the oxygen is low	Replace the oxygen tank with a new one. Prepare the oxygen tank for its filling
	The input pressure is low (less than 2,8 bar)	Verify the distribution system , or verify the performance of the pressure reducer by the manufacturer
The patient can't breath	The patient valve is not correctly positioned or is damaged	Verify that the patient valve is correctly positioned or replace it
The pressure inside patient's airway is not enough	non-rebreathing valve is not properly mounted on the tube and/or to the mask	Check the proper connection
High pressure alarm	The airways are obstructed	Ensure that implants have been removed ; bronchoaspiration has been carried out?
	The corrugated tube is bent	Verify the corrugated tube
	Patient is not hyperextended	Hyperextend or use Guedel or Berman cannulas
The manovacuometer doesn't indicate "0" when the ventilator is not working	The component is damaged	Put the device out of service and contact an authorized service center
Turning on the device it does not start the controlled ventilation	Failure of the pneumatic supply or a failure of the device has occurred	Check for visual or acoustic signals as described in this manual. If no signal is present, put immediately the device out of service and contact and authorized service center
The quick connector for the input of the medical gas is not stable	Quick connector damaged or worn	Put the device out of service and contact an authorized service center
Noises occur caused by vibrations when driving the medical vehicle	Constant stresses caused a deterioration of the fasteners or mating surfaces	Ask your installer to check that the conditions for the installation have been met
The device does not turn on	Anomalies of the internal electronic circuit	Put the device out of service and contact an authorized service center

13.1 How to return for servicing

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 incorrect use. If the contamination is due to a malfunction, Spencer Italia S.r.l. will replace the product only in presence of a SALE RECEIPT. 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 disinfected on the outer casing with a cloth moistened with denatured alcohol or solutions containing hypochlorite and accessories immersing them in the same disinfectant. Place it in a bag with specified equipment and accessories disinfected. Request to specify the defect in order to carry out the repair in the shortest possible time. It therefore requires to carefully read the instructions to avoid compromising the device with inappropriate use. It requires you to specify the kind of fault to give way to the technical Spencer Italy S.r.l to judge whether the fault falls into the category of warranty.

14. ACCESSORIES

Standard equipment	
EV00106A	Patient circuit
EV30026	100cm Oxygen connection tube with UNI probe

Optional accessories	
EV00102A	Pediatric patient circuit
EV60030C	EVX 30 – PEEP autoclavable w/connector
EV60032C	EVX 32 – PEEP VALVE disposable w/connector
RM20800A	SPENCER MASK – FACE MASK.POLIS.STERILIZ.BLACK MIS.0
RM20802A	SPENCER MASK - FACE MASK.POLIS.STERILIZ.BLACK MIS.2
RM20804A	SPENCER MASK - FACE MASK.POLIS.STERILIZ.BLACK MIS.4
RM20805A	SPENCER MASK - FACE MASK.POLIS.STERILIZ.BLACK MIS.5
RM20810B	SPENCER MASK - FACE MASK KIT.POLIS.STERILIZ.BLACK 4 SIZES

15. SPARE PARTS

Spare parts	
RIEV009	Air connection tube 25cm for lung ventilator
RIEV010	Air connection tube 100cm for lung ventilator
RIEV011	Oxygen connection tube 60cm for lung ventilator
RIEV012	Oxygen connection tube 100cm for lung ventilator
RIEV013	Oxygen connection tube 240cm for lung ventilator
EV50111	KIT DISPOSABLE FILTERS LATEX FREE. (10 pz)

16. DEMOLITION

The components of the patient circuit, when no longer suitable for use, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations for demolition.