# User's Manual

# Spencer 118
## Pneumatic lung ventilator


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

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

## INDEX




First edition: 25/09/08
Rev. 5: 26/03/13



**Spencer Italia S.r.l.** • Strada Cavi,7 • 43044 Collecchio (PR) ITALY
Tel. +39 0521.541111 • Fax +39 0521.541222 • E-mail: info@spencer.it

**Thank you for choosing a Spencer product**

# 1. GENERAL INFORMATION

## 1.1 Aim and contents

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

## 1.2 Conservation of the instruction manual

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

## 1.3 Symbols used

| Symbol | Meaning |
|---|---|
|  | General or specific warning |
| SN | Serial number |
| CE 0123 | The product is compliant with the specifications of the Directive 93/42/CEE |
| I | ON |
| O | OFF |

## 1.4 Servicing requests

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) shown on the label applied on the box or on the device.

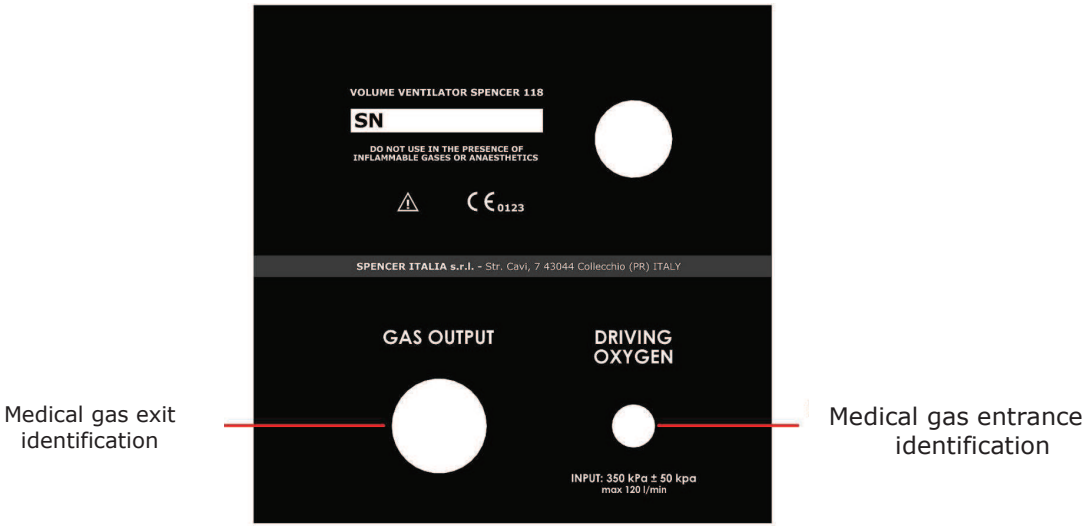
## 1.5 Demolition

Follow the current regulations.

## 1.6 Labelling

Each device is equipped with a label located on the device itself and/or on its packaging, in which appear the identification of the manufacturer, of the product, the CE marking, serial number (SN). This should never be removed or covered.

**Lateral panel**



## 2. WARNINGS

### 2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Check the device regularly. Perform the required maintenance and to respect the life span of the device, as indicated by the manufacturer in the user's 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.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Use of the device in anyway other than described in this manual is forbidden.
- Handle with care.
- With reference to the D. Lgs. 24$^{th}$ February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacturer as specified and within time given by the European regulations. In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users o any medical device.

### 2.2 Specific warnings

- The product must be used by trained personnel only**.**
- **The device is designed for use on emergency vehicles and not for home therapy.**
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption. If there isn't any another lung ventilator available, ventilation should be immediately restored by means of a device for manual ventilation (eg. Spencer B-life manual resuscitator) in order to ensure the life support functions. If required, the PEEP valve and the reservoir bag for the enrichment of oxygen may be associated with the manual resuscitator.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.

- The device has seals. If they have been removed or tampered with the manufacturer declines any responsibility for the product and for its correct functioning and for any consequent damage that may occur to the device.
- If the device comes with disposable accessories, these should be used for only one patient. They cannot be washed or re-sterilized after use, since the re-use can cause cross-infection.
- If the device comes with accessories with limited lifetime, do not use them after the expiry date printed on the package.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport device in its original packaging.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- The device must be used in a ventilated environment.

### 2.3 Contraindications and side effects

- Do not use the Spencer 118 electronic lung ventilator in neonatal clinics (0-18 months) and in patients with undrained pneumothorax.
- Do not use the device in presence of inflammable substances and anaesthetics.
- To avoid hypercapnia effects do not use 100% oxygen for protracted ventilation (the device is provided with a special mixer switch to change mixed oxygen/air to 60% or 100%).

## 3. DESCRIPTION OF PRODUCT

### 3.1 Intended use

Spencer 118 is an emergency lung ventilator with totally pneumatic power supply, operating at intermittent flow, time-cycled, pressure limited; it is capable of supplying two different concentrations of medical gas with a single power source gas.
It guarantees tidal volume and respiratory rate. An additional air valve allows the patient to breathe environmental air when the unit is not powered.
The interface with the user takes place by means of a front control panel made of a material resistant to abrasion and substances of common medical use. The front panel features an intuitive graphical interface.
On the right side the ventilator has got connections for oxygen under pressure and for dispensing the medical mixture to the patient. The non-rebreathing valve of the patient circuit is equipped with a special pressure limiter device for adults.
Its intrinsic characteristics and size make it particularly suitable for first aid, ambulance, patient transport, when you should replace the respiratory function in those patients without spontaneous breathing (ventilation system).
It is not expected that the patient can intervene on the device.

### 3.2 Main components and accessories

From the functional point of view the device can be regarded as composed of the following main components:

- **Frontal panel control**

All the control devices to operate the ventilator are lodged in this panel. It is made of scratch-resistant polycarbonate.

- **Pneumatic circuit**

Effects the integrated control of all respiratory functions and of the main parameters of respiration.

- **Patient circuit**

It consists of corrugated pipe in PVC, face mask Mask Spencer size 5, autoclavable non-rebreathing valve in polycarbonate, straight connector and antibacterial filter.

- **Oxygen connection tube 100 cm**

It allows connection of the ventilator to the oxygen source.
It contains phthalates DINP type.

### 3.3 Models

| | |
|---|---|
| EV01118 | Spencer 118 Pneumatic lung ventilator |
| EV02118 | Kompak 118 Resuscitation system |
| EV60118 | Porta Vent 118 Backpackable resuscitation system |

The codes listed above refer to the basic configurations, for more information contact Spencer Italia S.r.l.

### 3.4 Technical data

| | |
|---|---|
| **DIMENSIONS** | |
| Width | 295 mm |
| Height | 155 mm |
| Length | 160 mm |
| Weight | 3,5 kg |
| **MEDICAL GAS (OXYGEN)** | |
| Entry pressure | 3,5 bar ± 0,5 bar |
| Capacity | 120 L/min |
| **VENTILATION** | |
| Minute Volume | from 2 to 20 L/min |
| Volume released (measurable) | (volume/minutes):frequency |
| Ventilation frequency | from 5 to 40 BpM |
| Oxygen concentration | 60% or 100% |
| I/E Ratio | 1/2 |
| **MANOVACUUMETER** | |
| Tolerance | from -20 to +70 mbar |
| Range from -20 to +10 mbar | 2 mbar |
| Range from +10 to 70 mbar | 5 mbar |

### 3.5 Environmental conditions

| | STORAGE AND TRANSPORT | FUNCTIONING |
|---|---|---|
| **Temperature** | from -10 to +60 °C | from 0 to +40 °C |
| **Relative humidity** | from 5 to 100% | from 5 to 95% |
| **Atmospheric pressure** | from 50 to 106 kPa | from 70 to 110 kPa |

## 4. OPERATING INSTRUCTIONS

### 4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.
In case of long inactivity, besides the above-mentioned recommendations, the device must be stored with the precautions relevant to the place and time of stocking:

- Store the device in a closed place.
- Keep it from stress and impacts.
- Protect device from humidity as well as excessive thermal excursions.
- Avoid contact with corrosive substances.

### 4.2 Preparation

On receipt of the product:

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

If there is any damage relating to cartons or other packing material, contact the carrier and then the Customer Service Department or write to Spencer Italia Srl.
The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.
Put the device on a flat surface (i.e. shelf, trolley).
Check the integrity of the patient circuit and accessories and verify if the connections are correct.

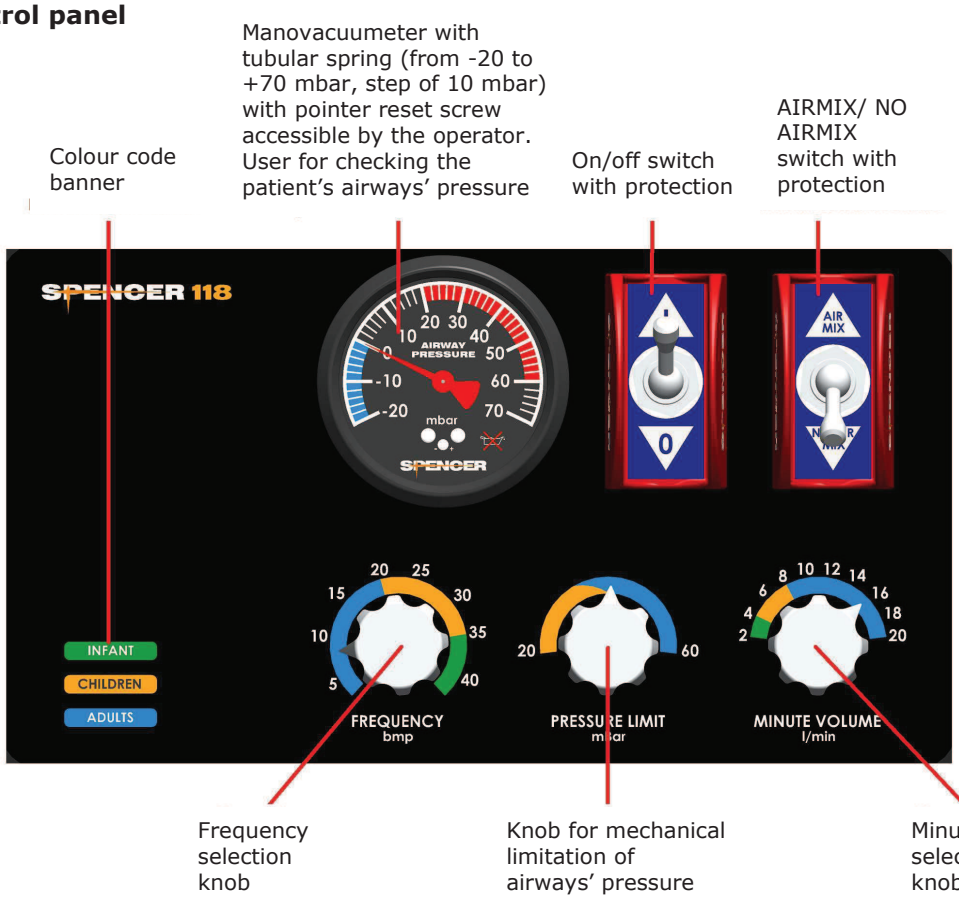
For the power supply of the ventilator use oxygen (centralized system or cylinder with pressure regulator) or compressed air at an inlet pressure of 3 to 4.5 bar and a minimum flow rate of 60 l/min.

### 4.3 Compressed air feeding

Use oxygen (central system or oxygen tank with pressure regulator) or compressed air with an entrance pressure from 3,5 bar ± 0,5 bar and a minimum capacity of 120 L/min.

## 4.4 Functioning

### 4.4.1 Control panel




### 4.4.2 Operating instructions

To use correctly and safely the product, follow the instructions below mentioned after connecting it with the power line:

- Connect the ventilator to gas supply 3,5 bar± 0,5 bar by an automatic outlet (in case oxygen is not available, compressed air may be used).
- Insert the autoclavable valve.
- Switch on the device ("I" position on the switch).
- Select the respiratory frequency.
- Select the minute/volume (Spencer 118 ventilator can supply an air/oxygen mixture from 2 to 20 L/min)
- Check that pressure gauge pointer is on zero position.

The device is able to replace the respiratory function in those patients who do not have spontaneous breathing (controlled ventilation). At any time the operator can see the situation of the real pressure of the patient's airways by observing the manovacuumeter on the front panel.
When turning on the device, the ventilator starts the default controlled mode: erogation of medical gas to the patient starts in cycles at regular intervals, in correspondence with the relevant frequency selected by the command.
The current volume of mix sent to each breathing act is detected in the following way: read the set value on the "volume/minute" button and divide it by the set frequency.
In order to facilitate the use of the selection and suggest the correct values, the knobs of minute volume and frequency use bands of different colour.

| | | |
|---|---|---|
| **GREEN banner (infant)** | Frequency 35-40 BpM | 2-4 L/min |
| **ORANGE banner (child)** | Frequency 20-35 BpM | 4-8 L/min |
| **BLUE banner (adult)** | Frequency 5-20 BpM | 8-20 L/min |

The selection of "AIR-MIX" or "NO AIR-MIX" depends on the patient's requirements.

**It is essential to select the NO AIR-MIX mode in the case of polluted environment.**

**It is absolutely necessary to regulate first the ventilator volume and then pressure because a late volume regulation (l/min) would bring to an immediate change of the pressure limit. After choosing volume ventilation, keep closed with the palm of the hand**

**the exit outlet of the patient valve (where the mask is normally inserted), then regulate the pressure limit with the dedicated knob.**
**Hyperextend the head and seek, after inserting an oral-pharynx cannula in the patient's mouth with the dedicated manoeuvres, to guarantee clearness of the airways. Place the ventilation mask on the mouth and on the nose of the patient checking the adhesion of the soft part of the mask on the patient's face for a good holding system. Selection method of the volume/minute select knob prevents from value changing during functioning in case of accidental touch.**

| DURATION IS EXPRESSED IN MINUTES FOR A CYLINDER LOADED AT 200 BAR | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | FLOW SELECTED (Litres / Minute) | | | | | | | | | |
| Cylinder litres | 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 |

**Verify constantly during use the state of charge of the cylinder, so as to be able to have a correct management of the gas necessary for the operation, and assess possible replacement for the continuation of the resuscitation procedures.**

In case of intubation, leave the ventilation mask of the patient valve. Insert in the free hose the endo-tracheal tube with its connector.
Resistance of the airways due to obstructions or external cardiac massaging does not cause a variation of the respiratory volume frequency. In case of reduction of the compliance, the ventilator will react with a rise of respiratory pressure at a constant volume.

**Overpressure valve test**
After assembling and connecting the device to the relevant sources you can execute the following test: close the patient outlet with the palm of a hand and rotate the pressure limit knob to verify the pointer excursion on the gauge.

Once you have finished using the device, you must:
• Turn off the Spencer 118 through switch "O"
• Shut off the supply of oxygen

### 4.5 Troubleshooting

| PROBLEM | CAUSE | REMEDY |
|---|---|---|
| The ventilator does not work | The device is not connected to a source of gas (oxygen or medical air) | Connect the ventilator to a medical gas source |
| | The oxygen tank is empty | Replace it with another cylinder full of reserve and prepare the filling of the exhausted cylinder |
| | The pressure regulator is clogged | Clean the regulator, replace the filter (if possible) or replace the regulator |
| The ventilator works correctly but he patient cannot breathe | The patient non-rebreathing valve is positioned incorrectly or it is damaged | Check the fixing of the patient non-rebreathing valve or replace it |
| | The "non-rebreathing" valve is not adequately connected to the tube and/or mask compromising good holding | Adequately connect the "non-rebreathing" valve to the mask and corrugated tube |
| The ventilator works correctly but he patient cannot breathe | The patient non-rebreathing valve is positioned incorrectly or it is damaged | Check the fixing of the patient non-rebreathing valve or replace it |
| | Break of internal components | Contact the service centre |
| Internal leakage of the ventilator | Break of internal components or disconnection of internal pneumatic connectors | Contact the service centre |

| | | |
|---|---|---|
| While varying the position of the switch, the frequency does not change | Break of frequency regulator | Contact the service centre |
| The pointer of the manovacuumeter is blocked | Break of manovacuumeter | Contact the service centre |

## 5. MAINTENANCE AND CLEANING

### 5.1 Cleaning

The operations below described must be executed after each use of the SPENCER 170.

- Switch off the ventilator
- Isolate it from the power supply (if connected)
- Disassemble the non-rebreathing valve
- Check for the presence of residuals near the connection with the patient circuit and remove any
- Clean the surface points visible dirt with a damp disposable moistened with cleaning fluid.
- Autoclave the non-rebreathing valve, through a cycle validated EN ISO 11135-1.

**Do not filter cleaning fluid in the equipment.**
**The patient circuit tube is disposable: replace it after use.**
**To ensure compatibility with the materials, make sure to use, during the cleaning/disinfection, special "disinfectants for surfaces" as shown in the chart:**

| PRODUCTS WHICH CAN BE USED | PRODUCTS WHICH CANNOT BE USED |
|---|---|
| Disinfectants with aldehydes | Compounds that release halogens |
| Disinfectants with alcohol | Strong organic acids |
| Quaternary ammonic compounds | Compounds that release oxygen |

**During all operations control and sanitation, the operator must wear appropriate personal protective equipment such as gloves, goggles, etc.**

### 5.2 Maintenance

#### 5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

Checks to be carried out before and after each use, 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)
- Absence of cuts, holes, tears on the structure
- State of use

**The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage**. Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance warranty and will void 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.

### 5.2.2 Periodic maintenance

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

If above mentioned revision is not carried out the conformity to the Directive 93/42/CE for medical devices will no longer be valid therefore, even though the CE mark if present, it is possible that the device no longer answers all the requirements as indicated by the Manufacturer at 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.

### 5.2.3 Special servicing

**Only the Manufacturer or centres with written authorisation are authorised to complete any special servicing operations.**

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

The device, if used as indicated in the following instruction manual, **has an average life span of 5 years**. The life span can be expanded only following a general revision of the product that must be carried out by the Manufacturer or by a centre authorised by 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 repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorised Service centres. The warranty will be considered void, and the conformity to Directive 93/42/CEE Medical Devices will be no more valid.

## 6. ACCESSORIES

### 6.1 Accessories

| | |
|---|---|
| EV00106A | Patient circuit complete with antibacterial filter |
| EV50017B | Non-rebreathing valve |
| RM20400B | B-life resuscitation mask size 0 |
| RM20401B | B-life resuscitation mask size 1 |
| RM20402B | B-life resuscitation mask size 2 |
| RM20403B | B-life resuscitation mask size 3 |
| RM20404B | B-life resuscitation mask size 4 |
| EV20405B | B-life resuscitation mask size 5 |
| EV20216A | Fast connection inlet with tube holder |

### 6.2 Spare parts

| | |
|---|---|
| EV30020A | Oxygen connection tube |
| EV50020A | Corrugated tube in PVC ø22mm L=120 cm with rubber connectors |

**Avvertenza**

Le informazioni contenute in questo documento sono soggette a modifica senza preavviso e sono da intendersi come impegno da parte della Spencer Italia S.r.l. con riserva di modifiche. I prodotti Spencer vengono esportati in molti paesi nei quali non valgono sempre identiche regole. Per questa ragione possono esserci differenze fra quanto qui descritto ed i prodotti consegnati. Spencer lavora costantemente al perfezionamento di tutti i tipi e modelli dei prodotti venduti. Contiamo perciò sulla Vostra comprensione se dovessimo riservarci la facoltà di apportare in qualsiasi momento modifiche alla fornitura nella forma, equipaggiamento, allestimento e tecnica rispetto a quanto qui convenuto.