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SPENCER ITALIA S.r.l. Life Support

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Thank you for choosing

1 - GENERAL INFORMATION

1.1 PURPOSE AND CONTENT

The function of this Manual is to supply the Client with all the necessary information to both use the product in the correct way and to handle it confidently and safely. The Manual includes information regarding Technical aspects, Functioning, Maintenance, Spare parts and Safety.

1.2 MAINTENANCE OF THE USER MANUAL

The User Manual must be kept somewhere near the product in a purpose-made container, away from liquids and any other substance, which may alter the legibility of it.

1.3 SYMBOLS USED

SYMBOLS	MEANING	NOTES
	DANGER	Indicates serious danger, risk of death for the user.
	WARNING	Gives indications on the key functions or useful information. Pay attention to the text accompanying this symbol.

Before each use, read the instructions contained in this publication carefully.

In case of doubts on how to interpret the instructions, ask the manufacturer for the necessary explanation.

The device must be used only by specialized medical staff

2 - DEVICE DESCRIPTION

2.1 INTENDED USE

Spencer 118 is an emergency lung ventilator with completely pneumatic supply, no constant flow, time cycled, pressure limited; it can supply two different concentrations of medical gas with one gas supply source. It guarantees minute volume and respiratory frequency. An additional air valve allows the patient to breathe ambient air when the device is not supplied.

Interface with user is achieved by a front control panel realized in a material resisting to abrasions and to medical substances of common use. The panel graphics is clear and intuitive. On the right side the panel is provided with connections for oxygen and for medical gas supply.

The non rebreathing valve of the patient circuit, is provided with a pressure-limiting device, adjustable for adults and children.

Characteristics and small dimensions make it particularly suitable for first aid, emergency vehicles, patient transport, to substitute respiratory function in patients who do not breathe spontaneously (controlled ventilation).

2.2 MAIN COMPONENTS

Device is constituted by following main components:

- **Frontal control panel:** all the control devices to operate the ventilator are lodged in the control panel.
- **Patient circuit:** constituted by atoxic hose ø22mm and a non rebreathing valve.
- **Inlet**

2.3 TECHNICAL DATA AND DIMENSIONS

Height	80 mm
Width	240 mm
Depth	198 mm
Weight	2.2 kg
Box	Technopolimer
Controls	Frequency - Minute volume - Air mix/No air mix
Medical gas supply	3.5 ± 0.3 bar
Ventilation mode	controlled
I/E	1/1.5
Oxygen concentration	55% ± 100%
Frequency	5 ± 38 breaths/min
Minute volume	2 ± 18 l/min
Maximum working pressure	60 mbar
Airways pressure-gauge range	-20 ± +70 mbar
Pressure-gauge accuracy	from -20 to +10 mbar → 2 mbar from +10 to 70 mbar → 5 mbar

MEDICAL GAS (Oxygen or compressed air)

Inlet pressure from 3 to 4,5 bar
Minimum flow 60 l/min

2.4 ENVIRONMENTAL CONDITIONS

During operation:		During storage:	
Temperature	from +10° to +40° C	Temperature	from +10° to +65° C
Pressure	from 530 to 1100 hPa	Pressure	from 530 to 1100 hPa
Humidity (rel.)	from 5 to 95%	Humidity (rel.)	from 5 to 95%

3 - SAFETY

3.1 GENERAL WARNINGS

- Operators have to read this manual carefully, paying special attention to safety precautions and operating instructions.
- Use the device only as prescribed in this manual. Never alter or modify it: modification can cause unpredictable consequences and in this case Spencer declines every responsibilities.
- The utilization of the ventilator in power feeding and environmental conditions different from the indicated ones compromises the safety of operating.
- Ensure to execute periodically all preparation and maintenance operations described in this manual.
- If at any time device does not operate properly, take it out of service immediately and contact Customer Service.
- Ensure to have a manual resuscitator available to guarantee a continuous ventilation.
- Make sure that all precautions were taken to avoid hazards deriving from with blood or body fluids.

3.2 CONTRA-INDICATIONS AND UNDESIRABLE EFFECTS

- DO NOT USE ventilator in neonatal clinic and in patients with pneumothorax.
- DO NOT USE ventilator in presence of inflammable substances and anesthetics.
- To avoid hypercapnia effects, DO NOT USE 100% oxygen for protracted ventilations.

3.3 SAFETY SYSTEMS

The device is provided with the following safety systems:

Mechanical overpressure valve: maximum limits of device pressure 60mbar.

Overpressure valve on the patient valve (non rebreathing): valve enable if unlocked to limit the pressure to 40 cmH₂O.

Spontaneous breathing: when ventilator is off or gas supplying is interrupted, patient can breathe spontaneously.

3.4 LABELLING

Labels on the ventilator must not be removed or covered.

Please indicate the product serial number (SN) to make customer service easier.



4 - OPERATIONS

4.1 HANDLING AND STORAGE

Before handling the ventilator, be sure to have packaged adequately it.

To avoid damages handle it with care.

Preserve the original packaging for possible future handling.

Damages to the device caused by handling are not covered by guarantee.

Repairs or replacement of damaged components are at customer's expense.

Whether device is not going to be used for a long period, store it according to the following instructions:

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

4.2 ARRANGEMENT

At product receipt:

- remove packaging and set aside;
- check all the components: Spencer 118 and patient circuit.

If damages to packaging have occurred, first contact the carrier, then Spencer Customer Service at (+39) 0521 836182, or write to Spencer Italia S.r.l.

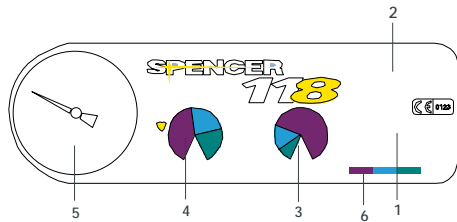
Check device before every use, to point out working defects or damages due to transportation or/and storage.

- Place device on a supporting surface - e.g. shelf or trolley -.
- Check integrity of patient circuit and accessories and verify connections to be correct.

Supply the ventilator with oxygen (central supply system or cylinder with pressure regulator) or compressed air from 3 to 4,5 bar and with a minimum flow of 60 l/min.

4.3 OPERATION

4.3.1 FRONT CONTROL PANEL



Legend

- On-Off switch
- No air mix - Air mix switch
- Minute volume knob
- Frequency knob
- Pressure-gauge

The legend (6) on the front panel specifies which colours are used to identify minute volume and frequency recommended values for different patient categories (adult, child, infant).

4.3.2 DESCRIPTION OF OPERATION

Device substitutes respiratory function of patients who cannot breathe spontaneously (controlled ventilation). In every moment attendant can visualize patient airways real pressure monitored by pressure-gauge on the front panel.

When device is on, it automatically operates in the controlled ventilation mode; thus gas supply starts. Medical gas is supplied to the patient at interval depending on the frequency value set by the control knob. Current gas volume supplied at every respiratory act depends on the minute volume set on the front panel by the control knob; it can be estimated dividing set volume by frequency.

To make selection easier and suggest values, on the minute volume and frequency control knobs, bands of different colours are used.

	Frequency	Minute volume (l/min)
RED (adults)	10-15	8-18
BLUE (children)	15-25	4-8
GREEN (infants)	25-30	2-4

AIR MIX - *NO AIR MIX* selection depends on patient's needs:

- *AIR MIX* (low oxygen concentration) is suggested for a medium/long use and when there is a small oxygen bottle.
- *NO AIR MIX* (high oxygen concentration): is absolutely necessary in case of air pollution.
- Be sure ventilator is in the OFF position when non-operating.

4.3.3 OPERATING INSTRUCTIONS

- Connect ventilator to gas supplying source by automatic outlet.
- Connect patient circuit and non-rebreathing valve.
- Switch on the device (I position on the switch).
- Select frequency.
- Select minute volume: the ventilator can supply an air/oxygen mixture from 2 to 20 l/min (in multiples of 2 litres).
- Check that pressure-gauge pointer is on 0.

4.3.4 TROUBLESHOOTING CHART

PROBLEM	CAUSE	ACTION
The ventilator does not work in switching "on" position	Ventilator is not connected to a medical gas or oxygen supplying source.	Connect the ventilator to a gas supplying source.
	Oxygen cylinder is exhausted.	Replace empty cylinder with a new one and arrange for its filling.
	Pressure regulator is obstructed.	Clean the regulator, replace filter (if possible) or replace regulator.
Ventilator works, but patient cannot inhale.	Non-rebreathing valve is not properly assembled.	Assemble correctly non rebreathing valve.
	Non-rebreathing valve is not connected to tubing or mask and it cannot guarantee gas-tight.	Connect adequately non-rebreathing valve to tubing and mask
Ventilator works, but patient cannot exhale.	Non-rebreathing valve is not properly assembled. Internal components are broken.	Assemble correctly the non-rebreathing valve. Contact Customer Service
Internal leaks.	Internal components are broken or internal pneumatic connections are disconnected.	Contact Customer Service
Moving the knob, frequency does not change.	Frequency counter is broken.	Contact Customer Service
Pressure-gauge pointer is locked.	Pressure-gauge is broken.	Contact Customer Service

5 - MAINTENANCE

5.1 CLEANING

Good care, cleaning and correct use of the ventilator are essential to obtain reliable, trouble free operation. Any mechanical device used in connection with patients must be periodically checked.

- Switch off the ventilator.
- Disconnect the patient circuit.
- Disassemble the non rebreathing valve.
- Check for residual substances near the patient circuit connection and remove them.
- Clean wiping visible dirty parts with a single use cloth soaked with detergent.
- Autoclave treatment is required for the non rebreathing valve (not exceeding 125°C)

Avoid detergent penetration into device.

Patient circuit tubing is single-use/to be replaced.

Make sure that cleaning and disinfection operations do not affect material integrity. Use for device surfaces following detergents:

PRODUCTS WHICH CAN BE USED	PRODUCTS WHICH CANNOT BE USED
Disinfectants with aldehydes	Compounds liberating halogens
Disinfectants with alcohol	Strong organic acids
Quaternary ammoniac compounds	Compounds liberating oxygen

Lack of cleaning can cause risk of cross-infections.

Check for ventilator functionality monthly, switching it on and operating for some minutes.

5.2 GENERAL REVISION

Device must be sent to manufacturer every year. It is then sent back with a final test report; this check concerns flow rate, frequency and incidental loss.

5.3 SERVICE REQUEST

Contact manufacturer for any information concerning use, installation, maintenance, etc..

5.4 DEMOLITION

Follow laws in force.

6 - ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

Basic version is provided with a patient circuit (EV00106A), constituted by atoxic hose ø22mm and a non rebreathing valve, and a quick connection inlet (EV20216A) to connect tubing to oxygen supplying system.

The following accessories are available upon request:

CODE	DESCRIPTION
RM20400B	B-Life Mask size 0
RM20401B	B-Life Mask size 1
RM20402B	B-Life Mask size 2

CODE	DESCRIPTION
RM20403B	B-Life Mask size 3
RM20404B	B-Life Mask size 4
RM20405B	B-Life Mask size 5

Spencer 118 KOMPAK (EV50118A) is available; it includes:

- Spencer 118
- B-Life Mask size 5
- Pressure regulator
- Oxygen cylinder 2 litres
- Transport bag with fixing system for lung ventilators and cylinder

6.2 LIST OF REPLACEMENT PARTS

Repair or replacement operations can be performed only by authorized personnel.

User can only replace accessories, whose interchange cycle depends on use frequency.

CODE	DESCRIPTION
EV00106A	Patient Circuit
EV50014C	Non Rebreathing Valve
RM20400B	B-Life Mask Size 0
RM20401B	B-Life Mask Size 1
RM20402B	B-Life Mask Size 2
RM20403B	B-Life Mask Size 3
RM20404B	B-Life Mask Size 4

CODE	DESCRIPTION
RM20405B	B-Life Mask Size 5
EV20216A	Quick connection inlet with connector
EV30020A	Oxygen connection hose
EV50020A	Pvc hose ø22mm with connectors
EV50025E	Silicone hose ø22mm with connectors

Warning

Reservation to make modifications. Spencer products are exported in many different countries worldwide, in which not always the same rules apply. For this reason there could be some discrepancies between the descriptions above and the products delivered.

Spencer continuously strives for perfection in the production of all product types. We therefore count on Your understanding if we make any ameliorating modifications, which may differ in shape, equipment, installation and technique to the above descriptions.