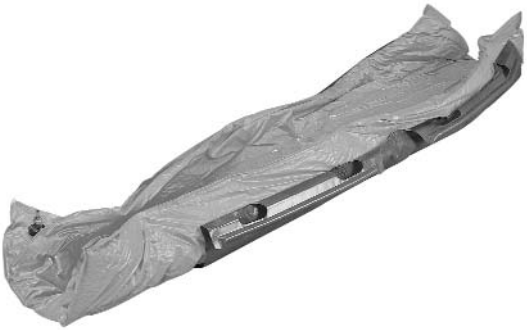
User's Manual

Vacuum Mattresses
Nexus - Combimatt



COMBIMATT

NEXUS

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 Product Service GMBH.

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Thank you for choosing a Spencer product

1 GENERAL INFORMATION

1.1 AIM AND CONTENTS

The aim of this manual is to supply all the information necessary so that the client, apart from attaining an adequate use of the appliance, 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 with the product, 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
	See instructions for use

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on 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 the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the lot number (LOT) on the label.

2 WARNINGS

2.1 GENERAL WARNINGS

- Before carrying out any kind of operation on the appliance, 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.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia Srl, for any necessary clarifications.
- Regularly check the appliance. Carry out the prescribed maintenance in order to keep the appliance in good condition and to guarantee correct functioning and a long life.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning, and the safety, the appliance 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, in such cases all responsibility will be denied for any malfunctions or eventual injuries caused by the appliance itself.
- Who modifies or has modified, prepares or has 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.
- Ensure that all the necessary precautions are taken in order to avoid hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

2.2 SPECIFIC WARNINGS

- The device may be used by trained personnel only.
- It is recommended to try the device without any patient before actually using it, to be sure to have acquired familiarity with the various manoeuvres.
- At least two physically suitable operators are requested for the use of the device.
- It is not possible, using only the device, to lift significant weights (> 15 kg) and maintain guarantees for good stability and indeformable support.
- Before every transport and/or movement, it is absolutely necessary to assure the patient on the device with use of the apposite belts. After that, the patient / device combination has to be fixed to the stretcher with at least two safety belts.
- Do not operate if the weight is not distributed correctly.
- Do not leave the patient without assistance when the device is in use.
- The device may not be exposed to, or get in direct contact with any type of heat source or inflammable agents.
- In case of anomalies or damages which may compromise the functionality and the safety of the device, the device must be taken out of service immediately.
- Pay maximum attention to possible obstacles on the route of transport of the device.
- During transport, make sure the patient's hands, feet or other body parts are inside the device, in order to avoid bumps or shocks that may cause lesions.
- Make sure to have taken all precautions in order to avoid any direct contact with blood or body fluids.
- The device is pressurized and therefore influenced by environmental pressure.

2.3 PHYSICAL REQUIREMENTS OF THE OPERATORS

Vacuum mattresses may be used in professional environments only. The operators working with the device mush possess the following minimum requirements:

- suitable manuality in order to grab the device firmly with both hands;
- robust back, arms and legs for moving the device;
- good muscular coordination and physical capacities.

Operators must be trained in efficient and safe patient transport.
For this device, at least two string, balanced and well sensed operators are needed. For patient transport, loading and unloading in case of particularly heavy patients, rough terrains or particular and unusual conditions, more operators may be needed.

The capacities of every operator must be considered before determining his role in the use of the device.

2.4 CONTRAINDICATIONS AND SIDE EFFECTS

The use of this device, if used as described in this manual, does not present any contra-indications or collateral effects.

3 DESCRIPTION OF PRODUCT

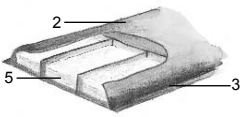
3.1 INTENDED USE

Vacuum mattresses NEXUS and COMBIMATT are patient immobilizing devices in case of suspected traumatic lesions, particularly useful for personalized immobilizations, referred to particular pathologic positions. The vacuum system allows different grades of immobilisation, from the most rigid one, which allows a correct positioning of the patient, to the more soft ones, which allow the absorption of low frequency vibrations, very common on emergency transport vehicles. Optimal mechanic immobilisers and thermal and electric isolates, highly adaptable.
The NEXUS mattress allows a decompression of the structure without as less deformation as possible in the thorax area, thanks to the presence of a wooden structure which guarantees the dimensions and the quality of the immobilisation.
COMBIMATT, thanks to a pocket with an expanded high densi polyethylene mattress, can actually be used as a stretcher mattress. The same pocket can be used for rendering the mattress more rigid and the transport more safe and efficient, by inserting a spinal board. The pocket can be closed with a strap system.

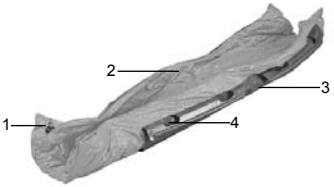
3.2 MAIN COMPONENTS

1. Aluminium decompression valve
2. Superior covering with longitudinal channels
3. External covering
4. Transport handles
5. Internal channels which contain Polystyrene spheres

Combimatt



Spaccato Interno



Nexus

The devices are made out of a PVC covering with 5 longitudinal channels, containing the polystyrene spheres, which are the functional part in obtaining a rigid structure during decompression.
The external covering in Nylon has a protective function in case of direct contact with various terrains. In the external structure, outside the patient immobilization surface, eight carrying handles are to be found which allow easy and safe patient transport.
On the two sides there are also mounted various buttonholes for the fixation of the safety belts.
The air evacuation takes place though a connecting tube between the metal decompression valve and a suction unit (manual or electric vacuum pump). Combimatt optimises the patient's comfort with the expanded closet-cell polyethylene mattress, indestructible, with limited weight and placed in the apposite pocket. The pocket, mainly used for the mattress, may be used for rendering the structure more rigid, by inserting a spinal board. Nexus has a reinforced inferior part, for two third of the total length, by two light and rigid marine multi-layer panels, in order to guarantee, apart from the real immobilization and antiretraction, spinal alignment support. The distal, inferior area can be shaped in order to optimise the immobilisation of eventual fractures of the lower limbs.

3.3 MODELS

QM22800A	Combimatt Vacuum mattress double use Orange/Blue
QM22900A	Nexus Vacuum Mattress Orange / Blue
QM22901A	Nexus Vacuum Mattress Orange / Blue with bag and vacuum pump Mod.120

3.4 TECHNICAL DATA

Characteristics	Combimatt	Nexus
Dimensions [mm]	2030x990	2020x850
Weight [Kg]	6,4	4,9
Superior covering	Tarpaulin 600 D	Tarpaulin 600 D
Inferior covering	Tarpaulin 700 D	Tarpaulin 1000 D
Separated chambers	X	X
Internal Material	Polystyrene spheres	Polystyrene spheres
Multi-layer wooden support		X
n° Nylon Handles	8 (4 every side)	8 (4 every side)
Unidirectional Aluminium valve	X	X

Characteristics	Combimatt	Nexus
Pocket for Spinal Board	X	
Antiretraction system		X
Tapered Distal	X	X
X-ray transparency	X	X
High frequency welding	X	X
Adaptable to Basket Stretcher		X
Compatibility Traction Systems	X	X
Loading capacity [Kg]	Max 150	Max 150
Weight limit for use without adequate supports [Kg]	Max 15	Max 15
Colour	Orange/Blue	Orange/Blue
Belts	n° 3 One-piece Orange Derlin clip	n° 3 One-piece Orange Derlin clip

The device, considering the materials used, reaches the point of fusion at about 100 °C.

3.5 ENVIRONMENTAL CONDITIONS

Both during use and warehousing, the device must be used according to the temperatures and relative humidity hereunder.
Functioning temperature: -10 °C to +50 °C
Warehouse temperature: -20 °C to +70 °C (in environments without risks for perforations and abrasions)
Relative Humidity: 15% - 90%

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

Fold the device, making sure the internal spheres are well distributed all over the structure, then slightly decompress, in order to reduce size and maintain the uniform sphere distribution.
Before transporting the device, make sure it has been packed adequately and there is no risk of shocking and falling during transport.
Conserve the original packaging for eventual transport. Damage caused during transport and movement are not covered by warranty. Repairs or substitutions are on charge of the Customer. Stock the device in a dry place.
During warehousing do not place any heavy objects on top of the device. The device is not to be considered a support in any way.

4.2 PREPARATION

When receiving the product:
- remove the packaging a dispose all material in a visible way;
- make sure all components and accessories, described in the transport list, are present.

Before every use, the device must be checked completely, in order to determine anomalies in functioning and/or damages caused by transport and/or warehousing.
Therefore, before every use check:
- general integrity of the device;
- absence of cuts, damages or hole on the covering;
- connection between the device and the unidirectional valve;
- state of use and held of the belts (if present);
- held and state of use of the handles.

If all conditions have been respected, the device may be considered ready for use.

4.3 FUNCTIONING

In extreme situations and difficult tracks a third operator is recommended.
The rescuer placed close to the head of the patient, is responsible for the development of the recovery operation, gives the orders and coordinates his colleagues.

Place the device as close as possible to the flank of the patient and verify the internal spheres are distributed in an uniform way all over the structure. If the terrain is not coherent or presents rocks or openings, place the device on the loading stretcher.

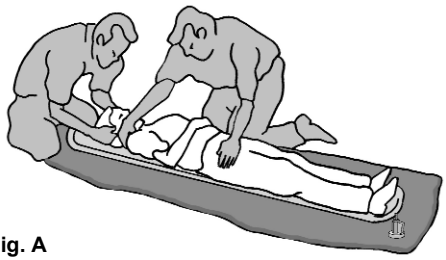


Fig. A

Load the patient on the device according to standard manoeuvres or with help of loading instruments (scoop stretcher - Fig. A). Place the patient on the device, with the feet pointing towards the decompression valve (Fig. B). The heels of the patient must go over the border: in this way it is possible to avoid compression of the vertebral column during decompression, when the device shortens.

Fig. B

Before starting the decompression, shape the device according to the patient, paying particular attention to immobilizing head, shoulders, body and inferior limbs (Fig. C). Shape the device in order to obtain a suitable shape for blocking any nertial movement of the patient. The containment manoeuvre must be kept during the entire decompression procedure. Make sure the device closes well around the patient and that the decompression does not cause any movement (Fig. C).

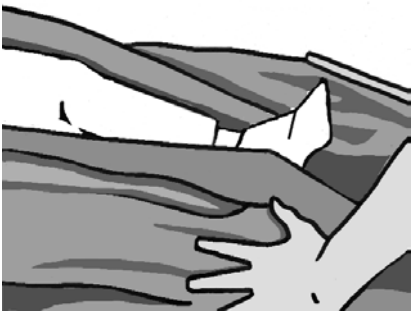


Fig. C

Controlling the immobilization of head and shoulders is one of the most important things, make sure there is a good adherence and control very well the retraction. (Fig. D). It is recommended to place a weight behind the head of the patient (for example operator's knee) during decom pression. Shape the device accurately according to the patient, without blocking head and feet in order to avoid compression of the vertebral column during transport. The first phase of decompression may be performed with an electronic vacuum pump, but the final part should be performed with a manual pump.

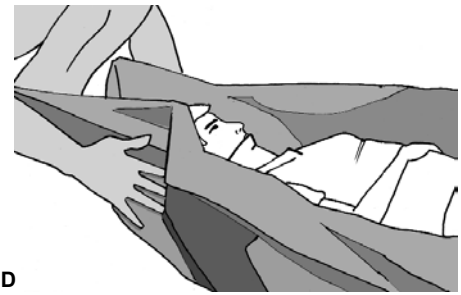


Fig. D

Make sure the valve is accessible at any time, also during transport. Is it recommended to expose it before loading and transporting the patient (Fig. E).

Fig. E

Once the requested pressure is reached, close the valve and detach the vacuum pump. In particular situations with height-variations (significant increase) it is recommended to keep the vacuum pump connected to the device for adjustments (Fig. F).

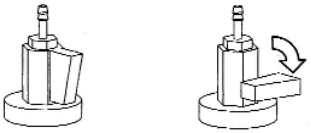


Fig. F

4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The device hardens during height decrement	Variation of the relative pressure	Check the real state of pressure of the device by opening the valve or proceeding with ulterior decompression. If the problem continues to exist, take the device out of service and contact the assistance centre.
The device looses decompression and tends to go back towards environment pressure	Deteriorated valve. Possible holes in the internal chamber	Take the device out of service immediately and contact the assistance centre.
No decompression of the device	Inefficiency of the pump or use/breakage of the connecting system between the valve and the device surface	Take the device out of service immediately and contact the assistance centre.
The device does not adapt to the patient's shape	Non conform material. Limited flexibility.	Take the device out of service immediately and contact the assistance centre.
Damage (holes, cuts, damages) to the external structure	Improper use or warehousing.	Take the device out of service immediately and contact the assistance centre.

5 MAINTENANCE AND CLEANING

5.1 CLEANING

Clean the exposed parts using flowing water, a sponge and delicate cleaning liquid, then dry with a soft cloth. Do not use high pressure water. Do not put in the washing machine.

Do not use instruments or liquids like metal sponges, aggressive degreasers or dissolvent (toluene, cilene, acetone). Do not use strong acids or bases.

Not cleaning the device regularly might create the risk of cross-contamination, because of the presence of body liquids.

5.2 MAINTENANCE

5.2.1 Precautionary Maintenance

No programmed maintenance operations are needed. Please remind regular cleaning as prescribed in paragraph 5.1 and the verifications of functionality before and after every use.

5.2.2 Servicing Maintenance

The person to whom the servicing of the appliance is entrusted must guarantee the following basic requirements:

- adequate knowledge of the appliance, of its technical/construction features, of checks and final tests, of packaging, conservation and handling;
- adequate knowledge of the technology used in the making of the appliance;
- knowledge of the functions of the appliance, of any potential risks and of the probability of possible malfunctions or break-downs;
- to be in possession of all the instruments necessary for carrying out any kind of technical operation regarding servicing;
- to be in possession of original replacement parts or those authorized by the manufacturer;
- specialized technical personnel trained by the manufacturer for the servicing of the appliance in question;
- guarantee complete adherence to the instructions of the 93/42/CEE Directive also regarding the obligation towards the manufacturer to allow the aforementioned a post sales care and traceability of the appliance when requested.

The device, if used as described in the following instructions, has a life span of 5 years.

6 ACCESSORIES AND REPLACEMENT PARTS

6.1 ACCESSORIES

DESCRIPTION	CODE
ABS pump Mod. 109 with double effect piston	QM22109A
Aluminium decompression pump with Spencer logo Mod. 120	QM22120A
Aluminium decompression pump NO Spencer logo Mod. 120	QM22121A
Aluminium decompression / compression pump Mod. 125	QM22125A
Transport bag for Nexus Vacuum Mattress Orange PVC	QM22902A
STX597 one-piece orange belt, Derlin closure	ST00597A
Repair Kit (Various sizes of covering material and glue)	QM22199A

6.2 SPARE PARTS

DESCRIPTION	CODE
Decompression valve	QM22051A
Repair element PVC Orange	QM22198A

Warning

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