SPENCER®

User's Manual

Mini Matt
Paediatric vacuum mattress

CE 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

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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 and maintenance manual

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

1.3 Symbols used

Symbol	Meaning
	General or specific warnings
	See instructions for use
LOT	Lot number
REF	Product code
CE	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 Servicing request

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, please contact the Spencer Customer Care Service tel. 0039 0521 541111, fax 0039 0521 541222, e-mail service@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 the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

1.6 Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the manufacturer, the product, the CE mark, the serial number (SN) or lot number (LOT). It must never be removed or covered.

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.
- 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.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on 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 to the device received, inform the manufacturer immediately and avoid use of the device.

- In case of any doubts about the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the manufacturer in this user's manual.
- 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 of the user are detected, the device must be immediately removed from service and the manufacturer must be contacted.
- 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.
- Use of the device in anyway other than described in this manual is forbidden.
- 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.
- Handle with care.
- 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.
- 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.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- 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.
- 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, 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 Manufacture 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.
- As a distributor or end user of products manufactured and/or marketed by Spencer Italia S.r.l., you are strictly required to have a basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the goods final destination Country (including laws and norms regarding technical specifications and/or safety requirements) and therefore you are also strictly 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. regarding any revisions to be made by manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, as specified in the relevant user's manual.

- Actively contribute to product safety checks on products sold, by communicating any relevant risk analysis information both to the manufacturer and to any competent authorities so that the necessary action 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 you will be deemed fully responsible for all damages that might occur. Therefore Spencer Italia S.r.l. expressly disclaims any responsibility and/or liability for your non-compliance with the present regulatory provisions.

2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying a reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the manufacturer in the user's manual.
- All maintenance and periodic check activities must be registered and collected together with their intervention reports (see Maintenance Register) 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.
- Use only components/spare parts and/or accessories that are original or approved by Spencer Italia S.r.l. in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Always respect the maximum load capacity of the device, as indicated in this user's manual. Maximum load capacity means the total weight distributed according to the human anatomy. In determining the load of the total weight on the product, the operator must consider the weight of the patient, the equipment and the accessories. Moreover, the operator must consider that the overall dimensions of the patient do not reduce the functionality of the device.
- Never leave the patient unassisted on the device, because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Follow the procedures approved by the Emergency Medical Service for the immobilization and transport of patients.
- Follow the procedures approved by the Emergency Medical Service for the positioning and transport of patients.
- Do not wash in a washing machine device.
- Do not use drying machines.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn, frayed or excessively worn out.
- Make sure, before lifting, that the operators have a firm grip on the device.
- Avoid pulling the device on rough surfaces.
- Do not lift by crane or other mechanical lifters.

2.3 Contraindications and side effects

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

3. DESCRIPTION OF PRODUCT

3.1 Destination of use

Versatile, easy to use and to clean. Thanks to the very limited dimensions it can be placed on every emergency vehicle, because paediatric immobilization must be done very quickly and perfectly. The handles made out of non-rotting polypropylene are soft and allow safe transport, also if used as a transfer sheet. The special tissue of the outside of the mattress protects it from damages caused by regular use and can be cleaned very easily.

3.2 Main components

1 Bag made of 400 D nylon
2 Polypropilene handles
3 Self-adherent strips closure

Fig. A

3.3 Models

QM30161A Mini Matt

These models could be modified, with reference to codes and/or descriptions without any previous notification.

3.4 Technical data

Dimensions (mm)	600 x 1300
Weight (kg)	2,2
Covering superior part	Nylon 400 D
Covering inferior part	Nylon 400 D
Internal pouch	Two high frequency welded PVC sheets
Internal material	Polystyrene
Temperature of use (°C)	-10 +40
Temperature of stocking (°C)	-20 +60
Aluminium one way valve	X
Handles	4
Radio compatible	X
HFW	X
Adapted for basket stretchers	X
Compatible with traction systems	X
Colour	Orange

3.5 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices
Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN 1865-1	Directives for stretchers and other patient transport equipment on ambulances
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1 /Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system

3.6 Environmental conditions

Functioning temperature: from -10 to +40 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 15 to 90 %

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.

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.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. In particular, check:

- 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

If the above conditions are met, the device may be considered ready for use; otherwise you must immediately remove the device from service and contact the Manufacturer.

4.3 Functioning

The rescuer at the head end of the patient is responsable for the recovery of the patient, and is the leader of the service. Position the device as close as possibile to the patient, at the same time checking the uniform distribution of the granular material container inside the mattress. If the ground is uneven, the device must be placed on a stretcher.

Fig. B

Load the patient on the device using a suitable technique or using the appropriate instruments (scoop stretcher fig. B). Position the patient, so that the feet are placed by the decompression valve (fig. C). The heels must be outside the border: this avoids a compression of the spine during the aspiration of air which causes shortening of the length of the device.

Fig. C

Before starting the decompression phase, you must shape the device to suit the patient, making sure that head, shoulders, pelvis and lower limbs are correctly immobilised (fig. D).
Shape the device to block any inertial type of movement. The containment manoeuvre must be maintained all the time of the decompression phase. Check the effective adhesion of the support to the patient in all points, making sure that the shrinking and hardening of the device causes no movement of the patient (fig. D).

Fig. D

The control on the part which immobilizes head and shoulders is very important; it is essential that this part is set tight and at the same time that the decompression is well controlled (fig. E). It is useful to apply some weight to the top of the device behind the head of the patient (knee of the rescuer resting on the ground) during decompression. Shape the device without restricting the area above head and below feet so as to avoid compression on the spine during transport. The first phase of decompression can be done with a suction unit, but the final part when the device is becoming hard, must be carried out with the appropriate manual pump.

Fig. E

It is important that the rescuer has easy access to the valve at any time during transport. It is recommended to expose it before loading and transporting the patient (fig. F).

Fig. F

When the desired is obtained, close the valve and disconnect the decompression device. In particular situations where high excursions in altitude are possible (substantial increase), it is recommended to keep the suction device connected (fig. G).

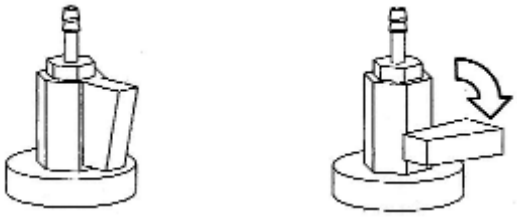

Fig. G

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The device stiffens as the altitude lowers	Variation of relative pressure.	Check the real state of pressure of the device opening the valve or further decompressing it using the pump. If the problem persists put the device out of use and contact the customer service centre.
The device tends to lose vacuum and regenerates internally the atmospheric pressure level	Deteriorated valve. There may be holes in the internal chamber.	Put the device out of use immediately and contact the customer service centre.
The device will not decompress	Either the pump or the connector to the device or the space between valve and device is worn out or broken.	Put the device out of use immediately and contact the customer service centre.
The device does not suit the patient's shape	The material of the device is not adeguate. Limited flexibility.	Put the device out of use immediately and contact the customer service centre.
Lesions (holes, cuts abrasions) to the external cover	Improper use. Incorrect stockage.	Put the device out of use immediately and contact the customer service centre.

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Clean the exposed parts using water and a soapy sponge or delicate detergent, then dry with a soft flanel or leatherette cloth. The use of high pressure water must be avoided. Do not machine wash. Avoid in any case cleaning products or detergents like metal sponges or blades, aggressive solvents or oil detergents (like toluene, cilene, acetone). Do not use acids or strong basics.

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals.

During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.

The exposed metal parts are usually treated and/or painted in order to increase their resistance.

The board has been made out of incontaminable material, in order to increase hygiene and easy cleaning.

Clean the exposed parts with water and delicate soap then dry with a soft cloth. In order to obtain a shine effect, it is possible to use car waxes and creams.

Do not clean with high pressure water; this will damage the joints and the lubricated parts.

If the trolley is not cleaned regularly, this may cause risks in terms of cross-contamination.

We recommend the use of the polishing detergent Spencer STX 99.
Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which could degrade or compromise the integrity and durability of the device. The use of high pressure water should be avoided. Water penetrates the joints and removes the oil, creating the risk of corrosion of components.
Allow to dry thoroughly before storing. Drying after washing or after use in wet environments must be natural and not forced, do not use flames or other sources of direct heat.

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.

During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.
Checks to be carried out before and after each use, and at least every 3 months, 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

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.
The person responsible for routine maintenance can identify damaged/worn parts, but the replacement or restoration of the them can only be done by the manufacturer or or by an authorized service center.
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

Planned interventions by the Manufacturer or authorized center are not required, but it is prescribed to make cleaning and checking indicated in the specific sections "Cleaning" and "Precautionary Maintenance".

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.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

QM22109A QMX 109 ABS pump for vacuum mattresses
QM22120A QMX 120 Aluminium vacuum pump for vacuum systems
QM22125A QMX 125 Aluminium vacuum pump for vacuum systems

6.2 Spare parts

There aren't any spare parts for this device.

ATTACHMENT A – TRAINING REGISTER

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

Keep this document at least 10 years from the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc.)	Trainer
	Basic training	Advanced training		

ATTACHMENT B – MAINTENANCE REGISTER

Keep this document at least 10 years from the end of life of the device.

Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

Code and description of the device	
Purchase date	
Lot (LOT) or serial number (SN)	
Bought by	

SERVICE DATE	KIND OF SERVICE (Maintenance / check / extension of life span)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (Operator / Authorized centre / Manufacturer)

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.

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