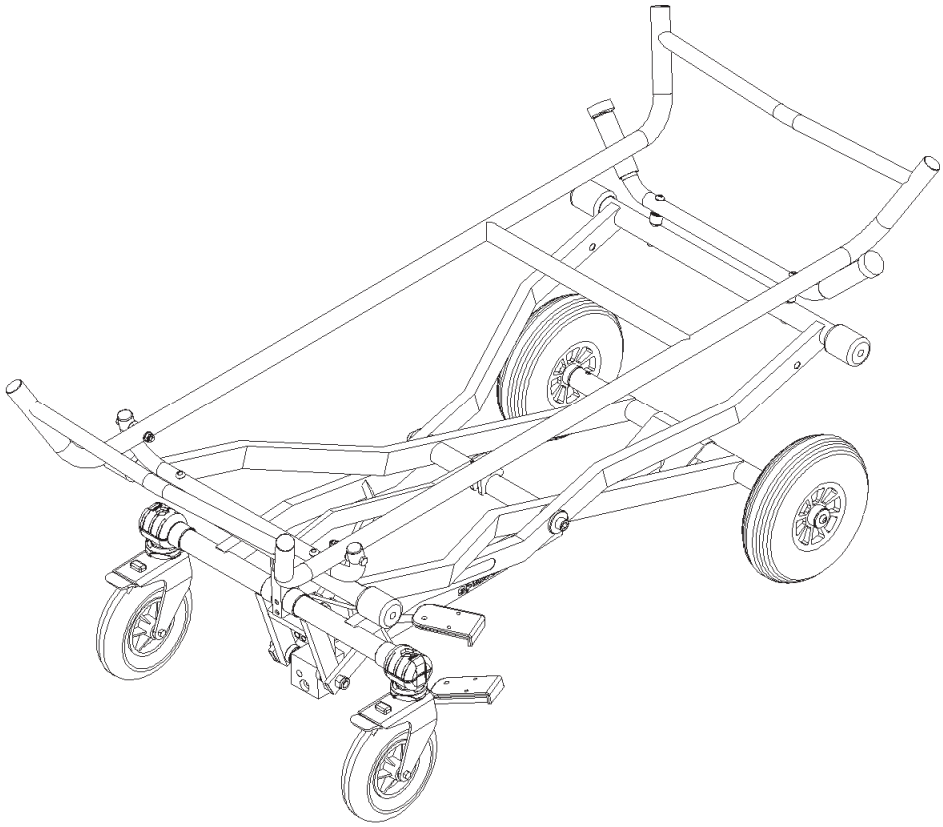
User's Manual

JACK S
Supporting frame for stretchers



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

General information	page 14	Operating instructions	page 18
Warnings	page 14	Maintenance and cleaning	page 20
Description of product	page 17	Accessories and spare parts	page 22

First edition: 20/06/11
Rev. 0: 20/06/11

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
	See instructions for use
	Lot number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE

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) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

Follow the current regulations.
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, CE mark, 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 available for conducting training courses.
- 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.
- Do not allow untrained personnel to help when using the device as they may cause injury to the patient or themselves.
- Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the 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 or 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.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- 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.

2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying an 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.
- 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.
- Use only accessories/spare parts 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 indicated in this User Manual. Maximum load capacity means the total weight distributed according to human anatomy. In determining the total weight of the load on the product, the operator must consider the weight of the patient, equipment and accessories. In addition, the operator must check that the size of the patient does not reduce the functionality of the device.
- Never leave an unassisted patient. Because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- The lubrication should be done after cleaning and drying.
- 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.
- Follow the procedures approved by the Emergency Medical Services for the immobilization and transportation of the patient.
- Follow the procedures approved by the Emergency Medical Services for recovery and transport of the patient.
- Avoid contact with sharp objects.
- Do not use the device if it is worn
- Make sure, before use, operators have a firm grip on the device.
- Avoid using the device on rough surfaces.
- Use the device first without patient to make sure that you have become familiar with it.
- The use of the device requires at least two operators in appropriate physical condition, they must therefore be equipped with strength, balance, coordination, common sense and should be trained on the proper functioning of the device.
- In case of particularly heavy patients, for working on steep terrain or under unusual or special circumstances it is recommended to have more operators (not just two as required under standard conditions).
- The maximum weight taken by each rescuer must comply with requirements prescribed by the laws of the Country, Occupational Health and Safety at Work.

2.3 Contraindications and side effects

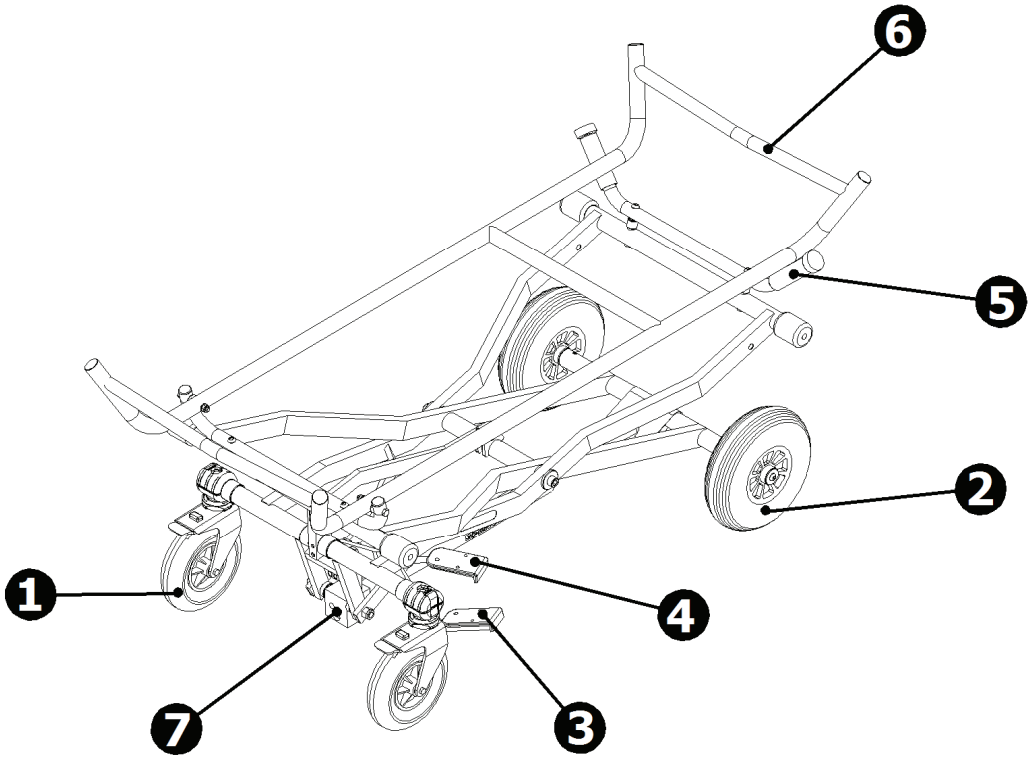
The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

Spencer Jack S is a special support with adjustable heights to fit any model of emergency stretcher. Jack S allows safe transport of patients thanks to an extremely durable structure.

3.2 Main components



n°	Component	Material
1	Wheel with bracket Ø 200 mm (2 pcs)	Polypropylene
2	Wheel Ø 250 mm (2 pcs)	Rubber
3	Up pedal	Steel
4	Down pedal	Steel
5	Rotating support for sliding	Nylon
6	Supporting frame for emergency stretchers	Aluminium
7	Hydraulic piston	Steel

3.3 Models

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

ST10260B	JACK S Supporting multilevel frame for stretchers

3.4 Technical data

TECHNICAL DATA	
Width (mm)	640
Length (mm)	1480
Height (mm)	1080
Weight (kg)	32
Load capacity (kg)	270

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 ISO 9001	Managing systems for quality: requirements
UNI EN ISO 9000	Managing systems for quality: basis and vocabulary
UNI EN ISO 13485	Medical Devices - Managing systems for quality – Requirements for regulamentation requirements
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN 980	Graphic symbols used for medical devices labelling
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation caractheristics 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
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans
BS OHSAS 18001	Managing systems for safety and health at workplace

3.6 Environmental conditions

Functioning temperature: from -20 to +50 °C
Storage temperature: from -20 to +50 °C
Relative humidity: from 5 to 95 %

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:

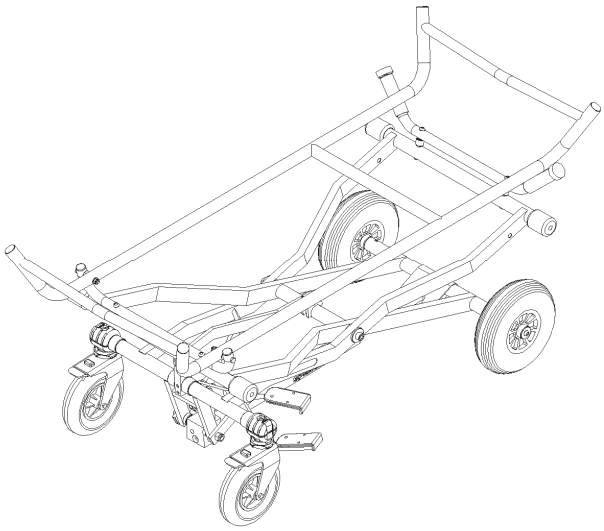
- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of no cuts, holes, tears on the structure
- Proper closure of screws and bolts
- Status of wear (moving parts, wheels)
- Integrity of components
- Lubrication of moving parts
- Wear of wheels and brake system
- The welds are intact, without cracking or breaking
- No pipe or sheet metal has cracks or bends

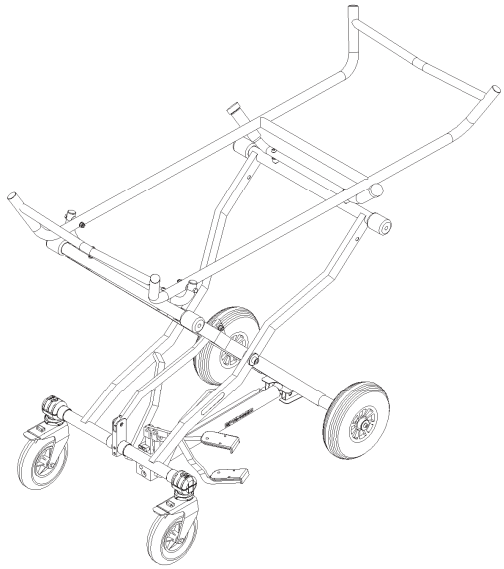
If the conditions above are met, the device may be considered ready for use, otherwise you must immediately remove the device from service and contact the Manufacturer.

4.3 Functioning

4.3.1 Raise and lower the device

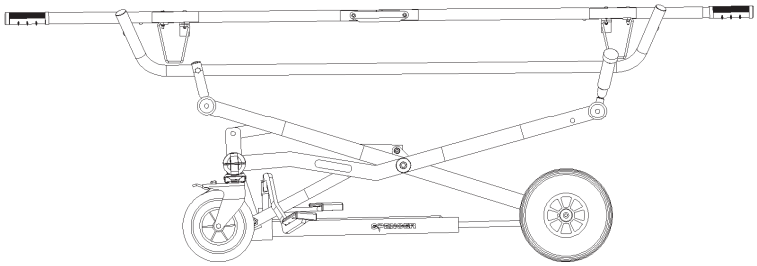
Insert the wheel brakes, acting on the levers, located on the brackets. Press the pedal up (3) to allow the lifting of the support frame (6) to the desired position, while for the phase of descent it is sufficient to keep the pedal pressed down (4).

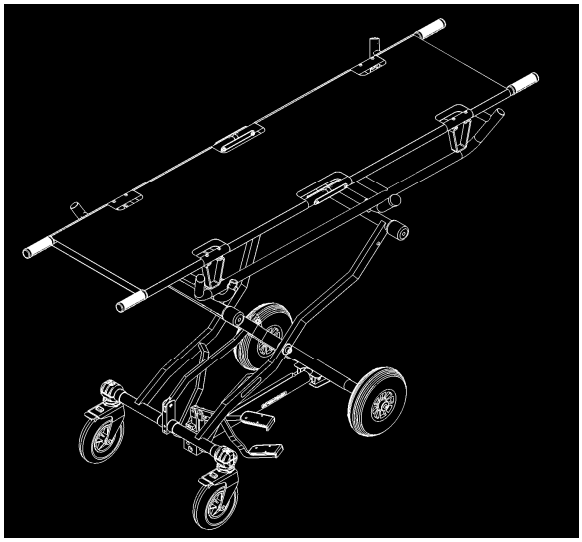




4.3.2 Loading of the emergency stretchers

Insert the brakes and fix the Jack S in the lowest position possible.
Place the emergency stretcher to have greater stability, with the support legs into the support frame. The Jack S is ready for use and can be raised by pressing the pedal to the desired height, moving it by turning off the brake.





4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Damages to the frame	Improper use	Put immediately the device out of service and contact the service centre
During the transport of the patient the device has difficulty moving	Brakes are still blocked	Unlock the brakes and check if the wheels are worn out
Difficulty lifting and lowering device	The cylinder of the hydraulic pump does not move or the pump doen not keep the pressure	Check that the pedals are released and not pressed, otherwise put the device out of service and contact the service centre

5. MAINTENANCE AND CEANING

5.1 Cleaning

Failure to carry out cleaning operations may involve the risk of cross infection due to the presence of secretions and/or residuals.

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

The metal parts exposed to external agents undergo surface treatment and/or painting in order to obtain better resistance. Wash exposed parts with warm water and mild soap, never use solvents or stain removers. In case of any disinfecting procedures do not use solvents wih corrosive action on the materials constituting the device. To get the brilliance of the chassis parts creams or waxes are recommended that are used for polishing the cars.
We also recommend the use of polish cleaner Spencer STX 99.
Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which may deteriorate or compromise the integrity and durability of the device. The use of high pressure water should be avoided. The water penetrates the joints and it removes the grease, 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

Establish a maintenance program and periodic testing, identifying an reference employee. The person who carries out the maintenance of the appliance has to guarantee the basic requirements indicated by the Manufacturer in the following paragraphs.
All maintenance activities, both precautionary and special, must be registered on documents including technical reports about operations. This register has to be kept for a period of at least 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.

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.

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
- Cleaniness of the device (remember that failure of the cleaning operation may cause the risk of cross infections)
- No cuts, holes, tears or abrasions on the whole structure
- Proper tightening of screws and bolts
- State of use (moving parts, wheels)
- Integrity of all components
- Lubrication of moving parts
- State of use of the wheels and braking system
- Welds are intact, without cracking or breaking
- No pipe or metal plate has bent or cracked

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. eclines 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 subject which is entrusted with the precautionary maintenance can only replace the parts listed in paragraph "parts". For other activities of replacing/repairing contact the manufacturer or an authorized centre.

Use only accessories/spare parts 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.

5.2.2 Periodical 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. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

6. ACCESSORIES AND SPARE PARTS

6.1 Spare parts

ST41603A	Bracket with wheel brake Ø 200 mm
ST42021A	Black Ø 200 mm wheel with bearing
ST70648A	Upper bumper for rear legs
ST70649A	Lower bumper for rear legs
ZC10100A	Pneumatic wheel 4”
ZC10103B	Black protection cap M8
ZC10108B	Vibration protection Ø 25 mm, 16 mm height
ZC10111B	Bracket with black wheel brake Ø 200 mm and screws

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)	
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)