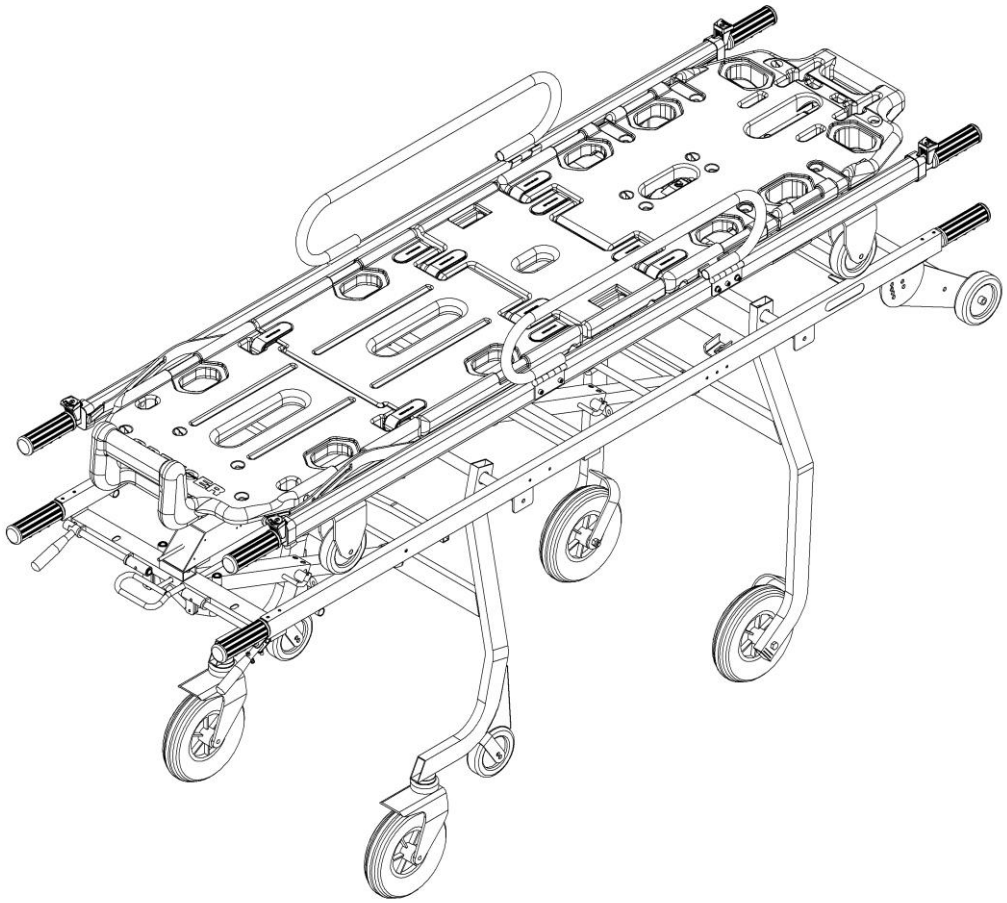
User's Manual

510 Self / 506
Self-loading separable stretcher



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

INDEX

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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, 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	Lot number
SN	Serial number
REF	Product code
CE	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 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 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

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) or serial number (SN). 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.
- At least every 6 months, is important to verify if updated User Manuals are available or there is any change involving your product. This information is freely available on the website http://support.spencer.it in the section "User manuals" and "Product Updates".
- 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 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 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 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.
- 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 of any medical device.
- As a Distributor or End Users 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 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.
- You are 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 we expressly disclaim 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.
- 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 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.
- Lubrication must be carried out after cleaning and complete drying.

- Follow the procedures approved by the Emergency Medical Services for the immobilization and transport of patients.
- Follow the procedures approved by the Emergency Medical Services for the positioning and transport of the patient.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn or frayed.
- 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 elevators.
- The device is a stretcher for patients transport and cannot be used as a stationing device.
- First practice with an empty stretcher in order to get used to the way in which the stretcher manoeuvres.
- For the use of the device, at least two operators in suitable physical conditions are needed; they must therefore have strength, balance, coordination, and common sense and must be trained on the correct functioning of the device Spencer stretcher.
- For techniques for loading particularly heavy patients, for rescue operations on steep ground or in unusual circumstances, it is recommended the presence of more operators (not just two as required under standard conditions).
- The maximum weight sustained by each rescuer must comply with requirements prescribed by the law of the Country, concerning Health and Safety at Work.
- Before each use, check the integrity of the belts and their hooks, as specified in the User's Manual. In case of malfunction or damage that may compromise the function and safety of the device, patient or operator, it is necessary to replace the belts.
- Make sure the belts are properly fastened to the frame of the stretcher.
- Always immobilize the patient, using the straps; lack of immobilization may cause serious damage.
- In order to meet the requirements of the standard UNI EN 1789, use only belts that have as anchor point the frame of the stretcher.
- To optimize patient's immobilization, is necessary to use a thorax belt secured to the frame of the stretcher in addition to the supplied ones.
- Make sure the mattress is properly secured/anchored to the frame /patient board of a stretcher.
- Make sure the sheet does not interfere with the footrest and do not prevent the operator from handling of the sidebars.
- Do not operate in case the weight has not been distributed correctly.
- The sidebars may be damaged due to improper use. Keep the sidebars always raised during patient transport.
- Always grasp the structure to lift and carry the stretcher and not the sidebars or polyethylene boards.
- Avoid extreme force during the loading procedure of the stretcher on the ambulance. Too much force may have negative effects on the functioning of the trolley.
- Keep the stretcher firmly if the patient is sitting.
- Use the stretcher only as described in this user's manual.
- Do not alter or modify the stretcher arbitrarily to make it fit into the ambulance: the modification may cause unforeseeable functioning and damages to the patient and operators. In any case the warranty will be lost.
- Pay a lot of attention to possible obstacles (water, ice, debris, etc.) on the route of the stretcher, because they could cause loss of balance for the operator and compromise the proper functioning of the device. If you can not set the path free from obstacles, choose an alternative path.
- For gradients greater than 10 cm, the device must be raised, taking care to grasp the structure and not from the banks/platforms.
- Condensation, water, ice and accumulations of dust can affect the correct operation of the device, making it unpredictable and causing a sudden alteration of the weight that operators have to carry.
- The self-loading stretchers are certified for use with dedicated Spencer fastening systems, it is therefore forbidden the use of fasteners not approved by the Manufacturer. Fastening systems that have not been approved may alter the structural and functional characteristics of the stretchers.
- Once positioned the wheels of the loading trolley on the support surface of the ambulance, the wheels of the front leg must have a distance from the ground of at least 6 cm. Check regularly the loading height of the ambulance; if it is altered, the stretcher must be immediately set up by the Manufacturer or by an authorized centre. Otherwise we assume no responsibility for the proper functioning or damage caused by the device itself.
- Improper installation of the loading platform may cause structural damage and consequent injury to the welding of the front legs.
- Improper installation of the loading platform may cause undesired operation of the device and cause harm to the patient and to the operator.
- Replace the wheels with original parts, in case of failure to stop the device.

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.

2.4 Physical requirements of the operators

Spencer 510 Self/506 is destined to professional use only. The rescue operators must have the following minimum requirements:

- physical capacity for operating the device
- be able to seize the device firmly with both hands
- have strong back, arms and legs for lifting, pushing and pulling the stretcher

• have a good muscular coordination

The operators must be trained in efficient, effective and safe patient transport.

This stretcher requires the employment of at least two operators equipped with strength, balance, coordination and common sense.

Patient loading procedures for extremely heavy patients, operations in rough terrain and in particular situations more operators may be needed (not only two as in normal conditions).

The capacities of the various operators must be considered before determining his role in the employment of the stretcher.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

Spencer 510 Self is a self-loading trolley indicated suitable to be used together with Spencer 506 trolley with telescopic handles. The union of the two devices generates a compact stretcher for patient transport, used for rescue operations on the road and on emergency vehicles, the legs bend independently during the loading phase, through the dedicated commands, and automatically open during the downloading phase. It has a security system on the legs (both front and rear) that trigger automatically when the stretcher is loaded on the ambulance. There is the possibility to lodge a spine board in the space between the trolley and the stretcher.

3.2 Main components

n°	Description of component	Material
1	Black wheel Ø 200 mm	Rubber polyurethane
2	Black wheel Ø 100 mm	Polypropylene
3	Telescopic handles	Aluminium
4	Support for adjustable loading platform	Steel
5	Fixed handle of trolley	Aluminium/rubber
6	Button for telescopic handles	Nylon
7	Folding sidebar	Steel
8	Backrest patient platform	High density polyethylene
9	Trendelenburg/Fowler patient platform	High density polyethylene
10	Lever for Trendelenburg/Fowler position	Steel
11	Posterior lever	Steel
12	Anterior lever	Steel
13	Pin for unlocking the stretcher	Steel
14	Pivoting wheel support Ø 200 mm	Steel
15	Anterior leg	Steel
16	Posterior leg	Steel

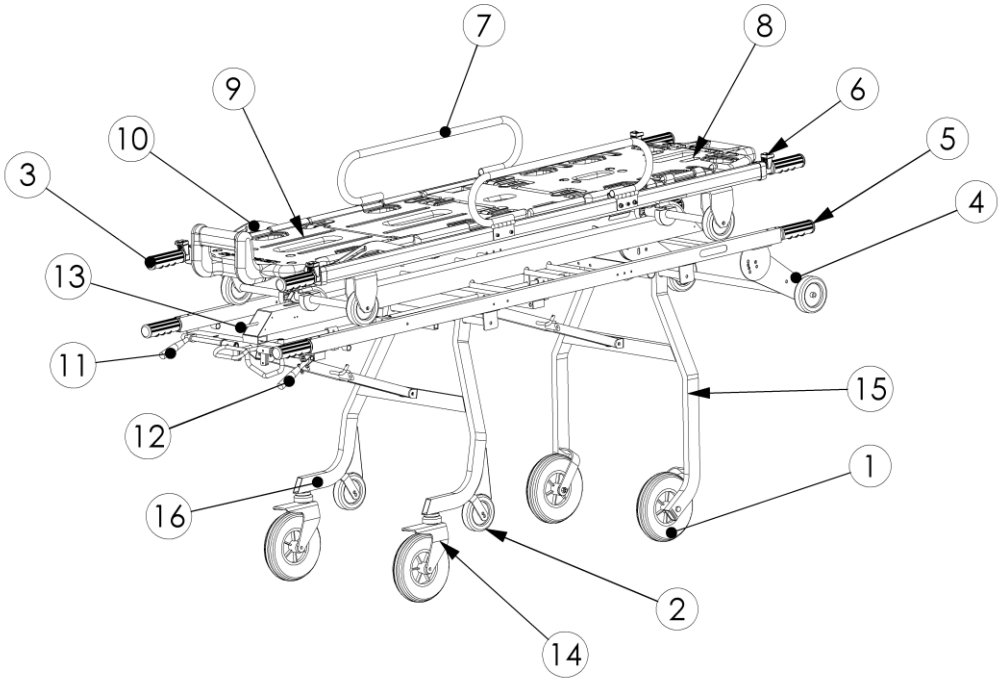

Fig. A

3.3 Models

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

ST10602C Spencer 510 Self silver
ST10603C Spencer 510 Self blue
ST60505A Spencer 506 S silver
ST60506A Spencer 506 S blue
ST60507A Spencer 506 TF blue
ST60508A Spencer 506 TF silver

3.4 Technical data

Characteristics	510 Self	506
Width (mm)	570	570
Length (mm)	1970	1970
Height (mm)	840	200
Weight (kg)	30	8

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 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 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
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans
UNI EN 1789	Medical vehicles and their equipment

3.6 Environmental conditions

Functioning temperature: from -20 to +60 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 5 to 85%

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, including the straps
- Correct fixation of all nuts, bolts and screws
- Correct fixation of straps
- Correct fastening of straps
- State of use (moving parts, wheels, belts)

- Integrity of components
- Integrity of handles (are they damaged or show signs of lacerations?)
- Lubrication of moving parts
- When taking out for the first time the stretcher from its box, the its legs should bend and lock properly
- Backrest and Trendelenburg work the same way and lock properly
- Sidebars are raised and lowered properly
- State of use of wheels and breaking system
- Functioning of springs
- The stretcher can easily get in the ambulance
- The emergency vehicle is equipped with a fastening system dedicated to the Spencer stretcher
- There are seat belts for the immobilization of the patient and they are intact and functioning
- Welding is intact, without any cracks or breaks
- No piping or metal sheet present bends or cracks
- The backrest has no structural damages or fissures
- The measure of the loading platform must be carried out after placing the ambulance on a uniform surface and free from any depression and/or gradient and after having placed the operators in the rear part of the sanitary cell (simulating a load of about 150 kg).

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 Requirements of the emergency vehicle

Spencer 510 Self / 506 have been designed for entering and exiting the patient compartment of an ambulance.
The requirements of the vehicle are:

- levelled loading platform;
- sufficiently wide and long platform with no obstacles for the stretcher;
- floor with a minimum height of not less than 50 cm;
- the fastening of the loading wheels must be at least 6 cm below the real measurement of the loading surface (this ensures the correct opening of the front and rear legs);
- to facilitate the insertion of the stretcher into the ambulance it is recommended to eliminate sharp edges on the edge of the loading floor of the ambulance;
- the stretcher must be secured to prevent any movement during ambulance transport in difficult driving conditions.

If the vehicle is equipped with pneumatic or hydraulic suspensions, the loading height adjustment must be carried out taking into account the worsening condition of use and/or the operating one provided by the vehicle builder.
Problems during use and/or safety risks associated with such system, cannot be attributed to the manufacturer.

4.4 Functioning

4.4.1 Lowering the stretcher

Make sure the side bars are positioned upwards; otherwise the stretcher may be damaged.
Lower the stretcher without patient, as follows:

- grab command handles of the 510 Self at the rear end "feet"
- lift the rear part "feet" of the stretcher, until the loading trolley wheels touch the ground
- pull both command handles in order to close the legs
- lower the stretcher, carrying its weight, until it touches the ground

Before loading the patient, while the stretcher is on the ground, make sure the surface is stable and horizontal; unstable and non-horizontal surfaces may affect the static balance of the stretcher.
is easier to manoeuvre in the open position, therefore, when possible, the stretcher should be brought at the desired point before lowering it.

4.4.2 Lifting the stretcher with patient

Fix the patient on the stretcher with the dedicated belts.
Two operators must be positioned at the edge of the stretcher (one at "feet" end, the other one at "head" end) and must verify that the leg blockage is not inserted.
Using an adequate lifting technique, make sure to grab the stretcher firmly at both ends. Lift the stretcher until the legs, front and rear, are open and completely blocked. Make also sure the underground is safe and stable

4.4.3 Loading the stretcher onto the ambulance

Make sure the ambulance's doors are blocked correctly in open position, in order to avoid any hindrances. Make sure the sidebars are blocked in upward position; otherwise the stretcher may be damaged. During the loading operation:

- push the stretcher towards the rear door opening of the ambulance;
- push the stretcher onto the loading platform of the ambulance until the front legs touch the edge of the ambulance (bumpers and/or platform);
- the operator must make sure both wheels of the loading trolley are placed on the loading platform (safety position) and contemporarily evacuate the distance between the wheels on the front legs and the terrain (at least 6 cm);

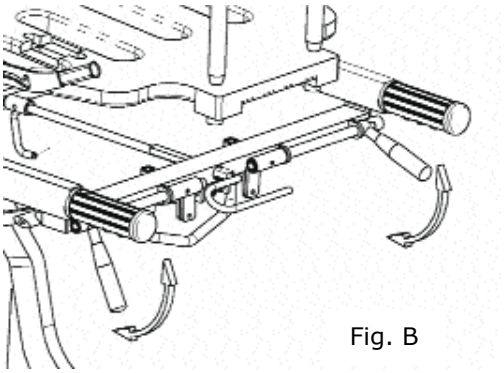

Fig. B

- once the front legs touch the ambulance's bumpers, the operator must pull the red handle for unlocking the front legs, without pushing the stretcher;
- once pulled the handle, push the stretcher inside the ambulance, allowing the front legs to fold and close; avoid extreme bumping of the front legs against the ambulance's bumpers and/or loading platform; legs and related mechanisms could be damaged;
- insert the stretcher into the ambulance until the rear legs touch the bumpers and/or platform, then lift the stretcher slightly and pull the green handle (left) unlocking the rear legs and complete the loading procedure of the stretcher;
- make sure the wheels of the loading trolley move into the dedicated anterior and posterior Spencer fastening systems;
- make sure the stretcher is securely fixed to the Spencer fixing system (if present).

The use of the original Spencer fixation systems is recommended in order to guarantee optimal stability in all directions. Whenever other fixation systems are used, the safety and correct functionality of the device are not granted.

4.4.4 Unloading the stretcher from the ambulance

Unlock the stretcher from its fixation system.
Grab the stretcher at the posterior tube of the frame ("feet" side) and gently pull the stretcher out of the ambulance. Make sure the stretcher remains horizontal until the safety position (the rear legs block automatically in the open position): the legs will open and block automatically. The operator must make sure the rear and front legs open up and block correctly. Make sure the underground is stable and secure before extracting the loading trolley wheels as well.

4.4.5 Brakes

The brakes can be inserted by pushing down the lever on the wheels. The brake system not only blocks the rotation of the wheel, but also of the complete wheel unit, offering complete immobilization of the stretcher.
To unlock the brakes, push the lever on the wheels.

4.4.6 Fixing the stretcher to the trolley

Apply the brakes on the lower trolley.
Place the stretcher above the trolley and rest on it, so that the guide rails engage on one another.
Slowly push the 506 stretcher toward the front of the 510 Self trolley actuating the locking hook present on it, thus forming a stable and secure system.

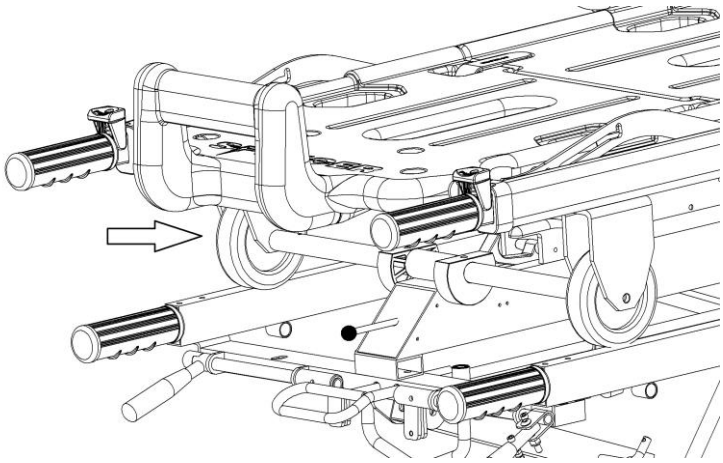

Fig. C

4.4.7 Removing the stretcher from the trolley

With the right hand pull the knob in back of the trolley and grab with the left hand the left knob of the stretcher and simultaneously pull it towards you.
The two operators, one in front and another at the rear, should grip knobs of 506 stretcher and lift it up.

4.4.8 Adjustment of the patient platform

Always inform the patient in case the patient board has to be adjusted.

Adjusting the backrest from horizontal to vertical position

Lift the backrest until the first position is reached and blocked automatically. Move the backrest further up in order to reach other intermediate positions (a total of seven different positions available and the horizontal position). Always make sure the backrest is blocked correctly.

Adjusting the backrest from vertical to horizontal position

Support the backrest with one hand (to avoid unexpected movements) and take away the weight from the backrest by lifting it slightly.
Action contemporarily on the lever, pulling it upwards until the security mechanism is unblocked. Then, always supporting the backrest with one hand, lower the backrest until the required position and let the lever go. In order to reach other positions, lift and support the weight of the backrest (a total of seven different positions available and the horizontal position). Always lift the weight of the backrest before pulling the lever.
A wrong procedure may damage the backrest piston permanently.

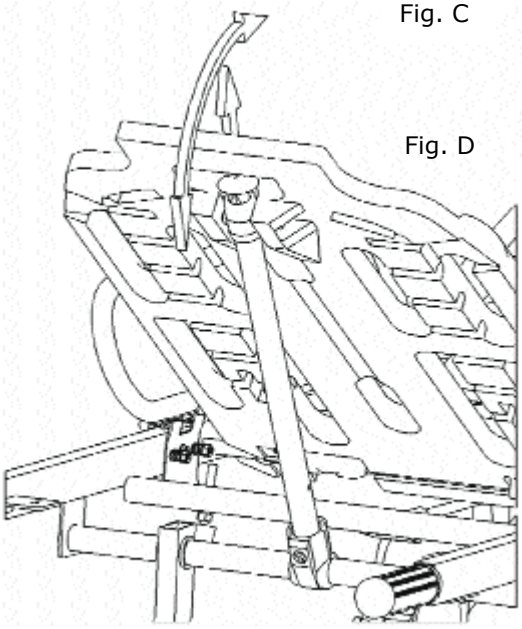

Fig. D

4.4.9 Trendelenburg/Fowler positions

The stretcher's patient platforms allow it to be moved according To the Trendelenburg and Fowler positions with

consequent raising of the lower limbs of the patient.
The Trendelenburg/Fowler system has three different position:

(a) The position 10-A of the system allows to tilt the two patient platforms so as to obtain an angle with its vertex facing upwards.

(b) The position 10-B of the system allows to maintain the patient platforms raised on the horizontal axis of the stretcher.

(c) The intermediate position between the two described above allows to maintain the patient platform of the stretcher horizontal.

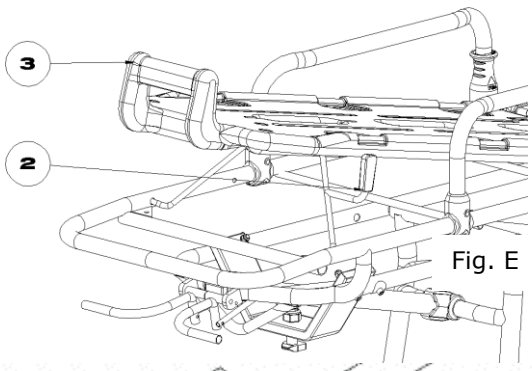

Fig. E

4.4.10 Foldable sidebars

In order to unlock the side bars, act as indicated by the arrows, first pulling up the blocking mechanism n° 17, then folding away the side bar n° 7 turning it. To put the sidebar back in upward position, action the blocking mechanism again, turn it in the opposite side and make sure it is blocked correctly.

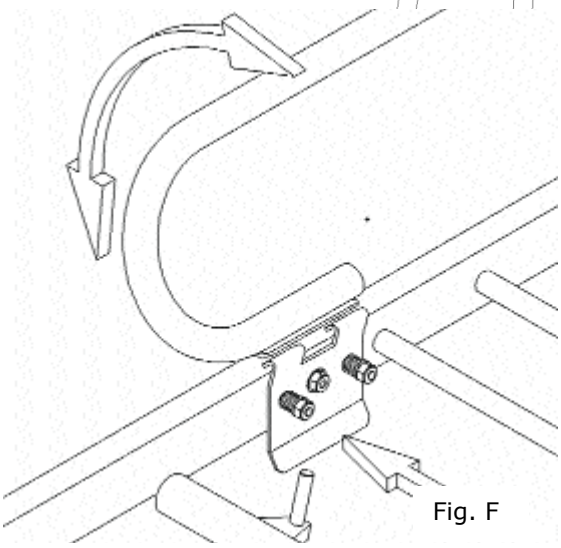
Fig. F

4.5 Troubleshooting

PROBLEM	CAUSE	REMEDY
The legs do not open when extracting the stretcher from the emergency vehicle	The rod for leg fastening is blocked	Unlock the rod for leg fastening
		If the problem persists, put immediately the stretcher out of service and contact the service centre
During patient transport the stretcher is difficult to move	The control handle has not been activated	Fully press lever
	The steel cables that transmit the linkage have been sliced	Put immediately the stretcher out of service and contact the service centre
During patient transport the stretcher is difficult to move	The brakes are still blocked	Unblock the brakes and check the condition of the wheels
Structural damage	Improper use or operators not adequately trained	Put immediately the stretcher out of service and contact the service centre

5. MAINTENANCE AND CLEANING

5.1 Cleaning

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

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

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 stretcher 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

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.
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.
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 of 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
- 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, including the straps
- Correct fixation of all nuts, bolts and screws
- Correct fixation of straps
- Correct fastening of straps
- State of use (moving parts, wheels, belts)
- Integrity of components
- Integrity of handles (are they damaged or show signs of lacerations?)
- Lubrication of moving parts
- When taking out for the first time the stretcher from its box, the its legs should bend and lock properly
- Backrest and Trendelenburg work the same way and lock properly
- Sidebars are raised and lowered properly
- State of use of wheels and breaking system
- Functioning of springs
- The stretcher can easily get in the ambulance
- The emergency vehicle is equipped with a fastening system dedicated to the Spencer stretcher
- There are seat belts for the immobilization of the patient and they are intact and functioning
- Welding is intact, without any cracks or breaks
- No piping or metal sheet present bends or cracks
- The backrest has no structural damages or fissures

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 them can only be done by the manufacturer or or by an authorized service centre.

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 the correct revision is not carried out, the CE branding will no longer be considered valid as it will no longer be compliant with the 93/42/CE Directive for Medical Devices and therefore there is the possibility that it is no longer compliant with the safety standards declared by the Manufacturer at time of 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.
Legs movement drive pistons , are components subjected to periodic replacement depending on intensity of use.
The following table shows some replacement intervals related to the number of average uses. The evaluation of needed maintenance, must be carried out by people responsible for maintenance of the device, according to this table.
The replacement is mandatory in order to ensure the safety of the product.

Intensity of use	**Heavy usage (over 30 times/month)**	**Medium usage (less than 30 times/month)**
Pistons replacement frequency	**Every 3 years**	**Every 5 years**

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, making void the guarantee and the conformity to the Medical Devices Directive 93/42/CEE.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

ST70002A	STX 702 Black belt two piece, metal buckle, Reflex
ST70000A	QMX 777 Black anatomic mattress, swivelling and watertight
ST70005A	QMX 777 Yellow anatomic mattress, swivelling and watertight
ST70004A	QMX 777 Orange anatomic mattress, swivelling and watertight
ST70019A	QMX 777 Green anatomic mattress, swivelling and watertight
ST70020A	QMX 777 Blue anatomic mattress, swivelling and watertight
ST70018A	QMX 777 Black anatomic mattress, swivelling and watertight without internal divisions
ST70006A	Belt for attachment to mattress
ST70011A	Tanker Cot careened oxygen tank holder 2 L
ST00497B	DNA Strap thorax belt system **
ST00498B	DNA Strap with integrated roll-up system **
ST00499B	STX 499 - UNIVERSAL ADJUSTABLE THORAX BELT
ST00592A	STX 592 - PLAIN BELT 2 PC. METAL BUCKLE
ST42022A	200 mm Ø high density wheel with bearings
ST42100A	Posterior fastener (FP) **
ST42200A	Anterior fastener (FA) **

**** Warning:** Doesn't meet the requirements of EN 1789 – Not suitable for use with 10G Certified Stretchers

6.2 Spare parts

LB01002A	Backrest patient platform in orange polyethylene
LB02002A	Central patient platform in orange polyethylene
LB03002A	Trendelenburg/Fowler patient platform in orange polyethylene
ST10610B	Bumper set for rear legs Ella Self with triangles
ST10611B	Bumper set for front legs Ella Self
ST10612B	Right sidebar Roller/Ella/506 in chromed iron
ST10613B	Left sidebar Roller/Ella/506 in chromed iron
ST10621B	Left lever for Trendelenburg with protection for Roller/Ella/506
ST10622B	Right lever for Trendelenburg with protection for Roller/Ella/506
ST10623B	Height regulator Ella Self Ø 25x15 M 10x45
ST10624B	Bracket for patient platform support Roller/Ella/506
ST10626B	Vibration-damping pad with 6x15 screw
ST10641B	Button for telescopic handles
ST10645B	Red knob handling front legs
ST10646B	Red knob handling rear legs
ST10907A	Fixed right handle for Ella Self with handle and fixation screws
ST10910A	Fixed left handle for Ella Self with handle and fixation screws
ST10918A	Bumper set for rear legs Ella Self
ST22400A	Ø 125 mm grey wheel with cushion, hole Ø 8, without support, without save row
ST41603A	Support with brake for 200 mm Ø wheel
ST42021A	200 mm Ø black wheel with bearings
ST42110A	100 mm Ø wheel with wheel axis pin

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)

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