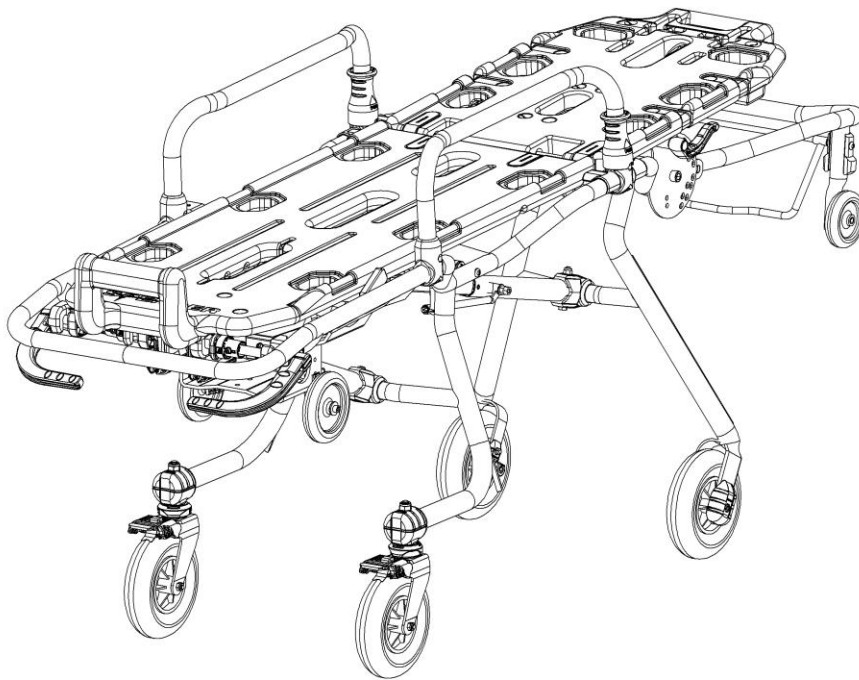


User's Manual

CROSS AMERICA 38

Roll-in stretcher with adjustable heights



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

General information	page 2	Operating instructions	page 6
Warnings	page 2	Maintenance and cleaning	page 8
Description of product	page 4	Accessories and spare parts	page 10

First edition: 01/03/12
Rev. 1: 09/04/12

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 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). 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.
- 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.
- 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 mm, 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 weldings 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 Cross America 38 stretcher 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 Cross America 38 is a self-loading stretcher with adjustable heights for patient transport. It is a compact and light stretcher, useable in rescue operations on the streets and on rescue vehicles. The legs fold away independently, activating the dedicated commands during the loading procedure, while, during the unloading procedure, they open automatically. The front trolley allows the stretcher to shorten significantly and its automatically adapting loading trolley allows loading on every loading platform. Spencer Cross America 38 is equipped with a safety system on both its legs, which is activated automatically when the stretcher is loaded on the ambulance. The rigid mono-shell board, moulded in high density polyethylene is easy to wash. Its colour is obtained by a patented pigmentation. Large diameter front (fixed) and rear (turning) wheels improve loading and transport.

3.2 Main components

n°	Description of component	Materials
1	Frame	Steel
2	Lever for Trendelenburg selection and reset	Steel
3	Trendelenburg board	Polyethylene
4	Folding sidebars	Aluminium
5	Backrest piston	Steel
6	Folding backrest	Polyethylene
7	Loading trolley wheel	Rubber polyurethane
8	Lever for stretcher shortening	Steel
9	Front legs	Steel
10	Wheels	Rubber polyurethane
11	Opening/closing piston for front legs	Steel
12	Rear legs	Steel
13	Turning rear wheels with brake	Rubber polyurethane
14	Opening/closing piston for rear legs	Steel
15	Front legs folding lever	Nylon
16	Rear legs folding lever	Nylon
17	Loading trolley	Steel
18	Handle for adjustable heights selection	Nylon
19	Safety lever of loading trolley	Steel
20	Sidebars blocking handle	Nylon

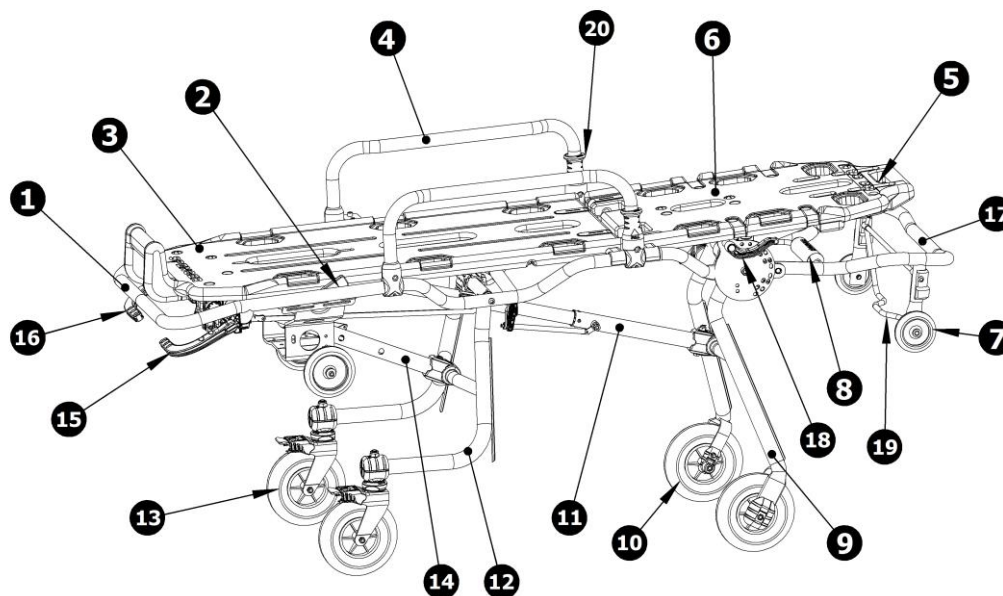


Fig. A

3.3 Models

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

CR11068E Cross T black patient board, yellow frame with DNA and QMX 777 for America 38

3.4 Technical data

Characteristics	Technical data
Width (mm)	570
Length (mm)	1970
Shortened length (mm)	1465
Sidebars length (mm)	630
Sidebars height (mm)	180
Weight (kg)	38,7
Load capacity (kg)	280

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 regulation 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 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
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 +60 °C

Storage temperature: from -20 to +60 °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 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
- 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
- Weldings are intact, no cracks or breaks
- No piping or metal sheet present bends or cracks
- The backrest has no structural damages or fissures

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.

THE MEASUREMENT OF THE LOADING PLATFORM MUST BE TAKEN WITH THE AMBULANCE POSITIONED ON A UNIFORM AND PERFECTLY HORIZONTAL SURFACE AND WITH TWO OPERATORS SEATED IN THE PATIENT COMPARTMENT (SIMULATING A LOAD OF APPROXIMATELY 280 KG).

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.

4.2.1 Requirements of the emergency vehicle

Spencer Cross America 38 has 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

Spencer Cross America 38 has been designed to have access to vehicles with a loading platform height between 450 mm and 550 mm.

Spencer Cross America 38 may not be used on loading platforms which do not respect the above mentioned limits.

The loading wheel fixation (n° 7 paragraph 3.2) must be at least 3 cm lower than the actual height of the loading platform (this will guarantee correct opening and closing of the legs of the stretcher).

In order to make the loading procedure easier, it is recommended to take away any edges from the border of the loading platform; the stretcher must be fixed in a way in which any movement of the stretcher will be avoided, also in difficult driving situations. Try out the loading and unloading procedures with an empty stretcher before putting the stretcher into regular service.

4.2.2 Loading the patient on the stretcher

Before transferring, lifting or transporting the patient, primary medical evaluations have to be performed. Once the diagnosis has been assured, it is preferred (if possible) to suggest the patient to collaborate actively during the transfer onto the stretcher, making sure the patient is fully aware of all risks. Before loading the patient, move it as close as possible to the patient.

4.3 Functioning

4.3.1 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 Cross America 38 at the rear end "feet"
- lift the rear part "feet" of the stretcher, until the loading trolley touches the ground
- pull both command handles in order to close the legs
- lower the stretcher, carrying the weight, until the rear part touches the ground

Before loading the patient, while the stretcher is on the ground, make sure the underground is stable and horizontal; unstable and non-horizontal surfaces may affect the static balance of the stretcher.

Brake the front wheels (optional) when the stretcher is on the ground and do not forget to unblock them before raising the stretcher.

Spencer Cross America 38 is easier to manoeuvre in an open position.

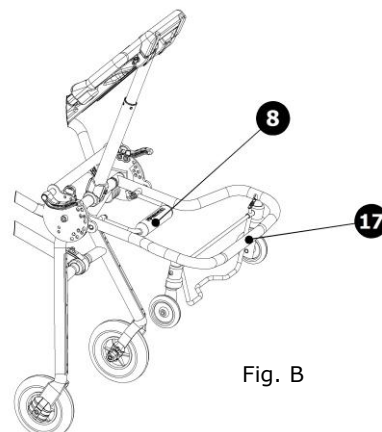


Fig. B

Therefore it is recommended to bring the stretcher as close as possible to the required position before lowering it.

4.3.2 Change length of the stretcher

In order to fit the Spencer Cross America 38 in small spaces (like hospital elevators), it is possible to reduce the maximum length of the stretcher, as follows:

- higher the backrest in vertical position
- action the lever n° 8, moving it up or downwards
- sustain the weight of the loading trolley (n° 17) and move it upwards in vertical position and make sure it is blocked in this position

4.3.3 Lifting the stretcher with patient

Fix the patient on the stretcher with the dedicated belts.

Two operators must be positioned in the following way: one at "foot end", one at "head end" of the stretcher. Using an adequate lifting technique, make sure to grab the stretcher firmly at both ends. Lift the stretcher until the legs are completely open and make sure the underground is safe and stable.

4.3.4 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 3 cm);
- once the front legs touch the ambulance's bumpers, the operator must pull the red handle, without pushing the stretcher (closing the front legs);
- 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; both 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 black (left) handle (closing the rear legs) and complete the loading procedure of the stretcher;
- make sure the wheels of the loading trolley move into the dedicated anterior fastening system (if supplied);
- fix the stretcher with the dedicated side fastening system (if supplied).

The use of the original Spencer anterior fastener and posterior fastener, fixation systems, is recommended in order to guarantee optimal stability in all directions.

Whenever other fixation systems are used, make sure they are functioning correctly.

In case the front and/or rear legs bump violently against the bumpers/loading platform of the ambulance, an automatic security system will be inserted in order to avoid the folding of the legs, even when the handles are pulled.

4.3.5 Unloading the stretcher from the ambulance

Unlock the stretcher from its fixation system.

Grab the stretcher frame and gently pull the stretcher out of the ambulance. Make sure the stretcher remains horizontal until the safety position (as described before): 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.

4.3.6 Adjusting the stretcher's patient board

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 (n° 6 fig. C). 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 the lever n° 21 (fig. C), 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.

Awrong procedure may damage the backrest piston permanently.

4.3.7 Trendelenburg movement

The Trendelenburg movement allows the lifting of the board in order to higher the legs of the patient.

Adjusting the patient board from horizontal to tilted position

Support and lift the board with one hand (n° 2 fig. C) taking away the weight.

Select the required position (two positions and the horizontal position), making sure the blocking system actually blocks the board.

Adjusting the patient board from tilted to horizontal position

With one hand lift the board slightly (n° 3 fig. C).

Push the Trendelenburg lever (n° 2 fig. C) and turn it downwards. Lower the board contemporarily with the lever until the horizontal position is reached.

4.3.8 Foldable sidebars

In order to lower the side bars, act as indicated in fig. E: first pulling up the blocking mechanism n° 20, then folding away the side bar n° 4. To put the side bar back in upward position, turn it up and make sure it is blocked correctly.

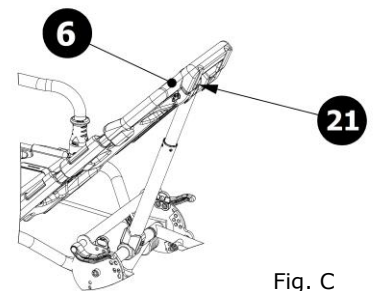


Fig. C

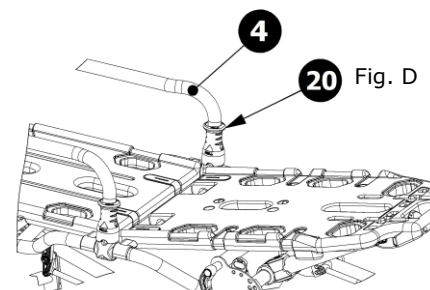
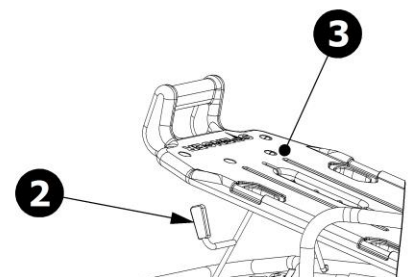


Fig. D

4.3.9 Intermediate heights

The Spencer Cross America 38 stretcher has been conceived in order to be able to assume different heights, making more easy the transfer of a patient from the stretcher to a bed and back, optimizing the loading procedures with elder or handicapped people. This stretcher is able to assume different intermediate heights, apart from the maximum height (completely open) and the minimum height (completely closed), as described below.

Passage from the standard to the intermediate heights

In order to reach the intermediate positions, at least two operators and the complete respect for the following indications are needed:

- Bring the stretcher as close as possible to the place of operations and make sure the underground is stable and safe.
- Support the weight of the stretcher at the rear end (feet/commands) and pull the left (black) lever, letting it go as soon as the stretcher starts to lower. Make sure the stretcher blocks correctly in a stable position.
- Pull the red blocking lever (n° 18 fig. F) upwards supporting the weight of the stretcher (loading trolley) until the stretcher reaches a stable position. If no patient is loaded on the stretcher, the loading trolley must be pushed downwards in order to reach the intermediate position.
- Insert the brakes on the rear wheels in order to stabilize the stretcher.
- Repeat the operation described in point (b), making sure the operator's hands are positioned correctly according to the position of the wheels and the frame of the stretcher, in order to avoid damages.

The combination of different intermediate heights, as described in (b) and (c) allows easy loading/unloading of handicapped patients.

Passage to the intermediate to the standard heights

In order to turn back to the original position of the stretcher:

- Grab the frame tube at the rear end of the stretcher (feet/commands) and pull it upwards until the first automatic safety block, making sure the stretcher has reached a stable position.
- Grab the frame tube on the front end of the stretcher (loading trolley) until the automatic safety block, making sure the red lever has returned in original position and the stretcher has reached a stable position.
- Proceed with the lifting of the rear end of the stretcher, repeating phase (a), making sure the stretcher has reached a stable position.
- Unblock the break on the rear wheels. Avoid lifting the stretcher at the footrest/board.

4.3.10 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 unblock the brakes, push the lever on the wheels.

4.3.11 Assembly of side stopper clevis

Place the side stopper near the sidebar and place the two half-shell components in the tube of the frame, securing them with the supplied screw. The locking pins should be fixed in the lower part of the two half-shells by tightening the longer screw.

4.3.12 Fixing the mattress to the stretcher

Place the mattress on the stretcher board, making sure the concave side is pointed upwards and the two rings are pointed towards the "foot end". Insert the "free" side of the strap (supplied with the mattress) from the upper side into one of the rings, until it automatically blocks with the plastic ring on the other end of the strap. Pass the strap under the board and pass it through the other ring from the lower side. Then fold the strap back down along the board, fixing it.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Pushing the stretcher against the vehicle's bumper, the legs do not fold away	The lever has not been actioned or the metal cable under the stretcher does not transmit the commands	Pull the lever, if the problem is not solved 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 the stretcher out of service immediately and contact the service centre
It is not possible to obtain the required position of the backrest	The backrest piston is blocked	Put the stretcher out of service immediately 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.

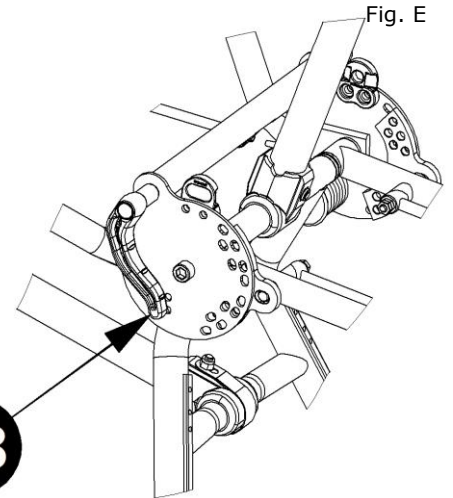
The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

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

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

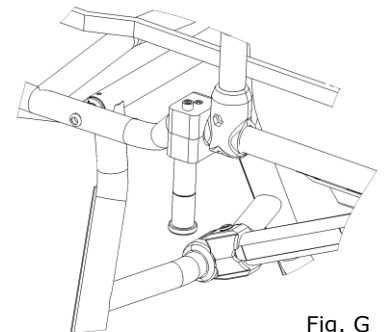
Clean the exposed parts with water and delicate soap, then dry with a soft cloth. In order to obtain a shine effect, it is possible to use car waxes and creams.

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



18

Fig. F



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

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
- 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 braking 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
- Weldings are intact, no 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 every day maintenance can substitute the spare parts indicated on paragraph 6.2 "Spare Parts", only if authorized by the manufacturer or by a centre authorised by Spencer.

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
ST70010B	QMX 777 Black anatomic mattress, swivelling and watertight with 10 G fixation
ST70018A	QMX 777 Black anatomic mattress, swivelling and watertight without internal divisions
ST70006A	Belt for attachment to mattress
ST70011A	Tanker Cot full fairing cylinder holder 2 L
IF01047B	Track 4-30 telescopic I.V. pole
IF01055B	Track 5 telescopic I.V. pole for Cross/Enduro
ST00497B	DNA Strap thorax belt with integrated retractor **
ST00498B	DNA Strap with integrated retractor **
ST00499B	STX 499 - UNIVERSAL ADJUSTABLE THORAX BELT
ST00592A	STX 592 - PLAIN BELT 2 PC. METAL BUCKLE
ST70002A	STX 702 BLACK BELT TWO PIECE, METAL BUCKLE, REFLEX

6.2 Spare parts

LB05005A	Trendelenburg board in polyethylene with footrest, black
LB01005A	Backrest board in polyethylene, black
ST41603A	Support with brake for 200 mm Ø wheel FE chromed
ST42021A	200 mm Ø black wheel with bearings
ST42110A	100 mm Ø wheel with wheel axis pin
ST70605B	Loading trolley block
ST70610B	Block for Trendelenburg command
ST70618B	Closing lever loading trolley with muff Ø 15 mm
ST70619B	Cross for loading board thread M12
ST70627B	Set front legs bumpers
ST70628B	Hinge in polycarbonate for side bars support without ring and small piston
ST70632B	Stabilizer left stretcher side bar in black nylon
ST70633B	Stabilizer right stretcher side bar in black nylon
ST70634B	Rear legs bumper, support with brake
ST70641B	Command pole for variable height
ST70646B	Red handle 15x4x5x6 for Trendelenburg movement
ST70647B	Set back legs bumpers
ST70648A	Top bumper back legs in nylon
ST70649A	Lower bumper back legs in nylon
ST70652A	Right hand support side bar movement, black nylon, with sp. el. 10x80
ST70653A	Left hand support side bar movement, black nylon, with sp. el. 10x80
ST70654B	Right hand side bar with support hinges, with sp. el. 10x80
ST70655B	Right hand side bar with support hinges, with sp. el. 10x80
ST70659B	Pivot holder for leg in black nylon
ST70665B	Kit side bumpers for front leg
ST70666A	Kit fixing hooks for new mould board
ST70677B	Kit interior red bumper for front leg
ST70700C	Red mechanism for side bar opening
ST70705B	Kit integrated lever and safety mechanism for handle
ST70706A	Kit couple of antivibration springs for stretcher supports
ST70708B	125 mm Ø wheel with tube and wheel axis
CR90021B	Wheels kit 60x25 Ø for loading more than 670 mm
ST42022A	Black wheel 200 Ø high density with bearing
ST70626A	Black wheel 200 Ø high density
ST42100A	Posterior fastner (FP)
ST42200A	Anterior fastner (FA)
ST42702C	Hook R-MAX B certified 10G
ST70003A	Footrest with screws (old model patient boards)
ST70674C	Manukit, stretcher maintenance kit
ST70691D	Allen keys kit for Manukit
ST70692D	Fork hexagon keys kit for Manukit
ST70693K	Plastic black box for Manukit
ST70664B	Kit for fixation of posterior fastner FP for stretchers
ST70704B	Breaker plate kit for variable heights for loading trolley

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.

© Copyright Spencer Italia S.r.l.

All rights reserved.

No part of this document can be photocopied, reproduced or translated into another language without the written approval of Spencer Italia S.r.l.