User's Manual

Spencer 480
Comfort chair with four wheels

CE This appliance conforms with the Directive 93/42/CEE "Medical Devices"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH

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Spencer Italia s.r.l.
Tel. +39 0521.541111 / Fax +39 0521.541222 / e-mail: info@spencer.it

www.SPENCER.it

Thank you for choosing a Spencer product

1. GENERAL INFORMATION

1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 Conservation of the instruction manual

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

1.3 Symbols used

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

1.4 Servicing request

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, please contact the Spencer Customer Care Service tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. – Via Provinciale, 12 - 43038 Sala Baganza (Parma) - ITALY. In order to facilitate the assistance service, please always indicate the lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

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

1.6 Labelling

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

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.

- If the instructions belong to another device and not 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 o 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 load capacity of the device, as indicated in this user's manual. Maximum load capacity means the total weight distributed according to the human anatomy. In determining the load of the total weight on the product, the operator must consider the weight of the patient, the equipment and the accessories. Moreover, the operator must consider that the overall dimensions of the patient do not reduce the functionality of the device.
- Never leave the patient unassisted on the device, because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- 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 the patient.
- 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 lifts.
- The device is a stretcher/chair for patients transport and cannot be used as a stationing device.
- First practice with an empty stretcher/chair 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/chair.
- 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/patient board of a stretcher/chair.
- Always immobilize the patient, using the straps supplied by the manufacturer; lack of immobilization may cause serious damage.

- Use the transport chair only as described in this user's manual.
- Do not alter or modify the transport chair 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 cannot set the path free from obstacles, choose an alternative path.
- For height gradients, 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 transport chairs 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 chairs.
- 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 480 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.

Patient loading procedures for extremely heavy patients, operations in rough terrain and in particular situations more operators may be needed (not only 2 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

The transport chair Spencer 480 is a device for the transport of patients in a sitting position.
The rigidity of the new frame, the padding of the seat and backrest, the larger surface of the armrests, the unprecedented release system make the transport chair agile, dynamic and above all, allow a great comfort for the patient
It is not expected that the patient can intervene on the device.

3.2 Main components

n°	Description of Component	Materials
1	Backrest cover	Padded PVC
2	Seat cover	Padded PVC
3	Armrest	Steel
4	Front telescopic handle	Aluminium
5	Footrest	Aluminium
6	Front pivoting wheel Ø100 mm with brake	Polypropylene
7	Rear wheel Ø200 mm	Rubber polyurethane
8	Rear handle	Steel

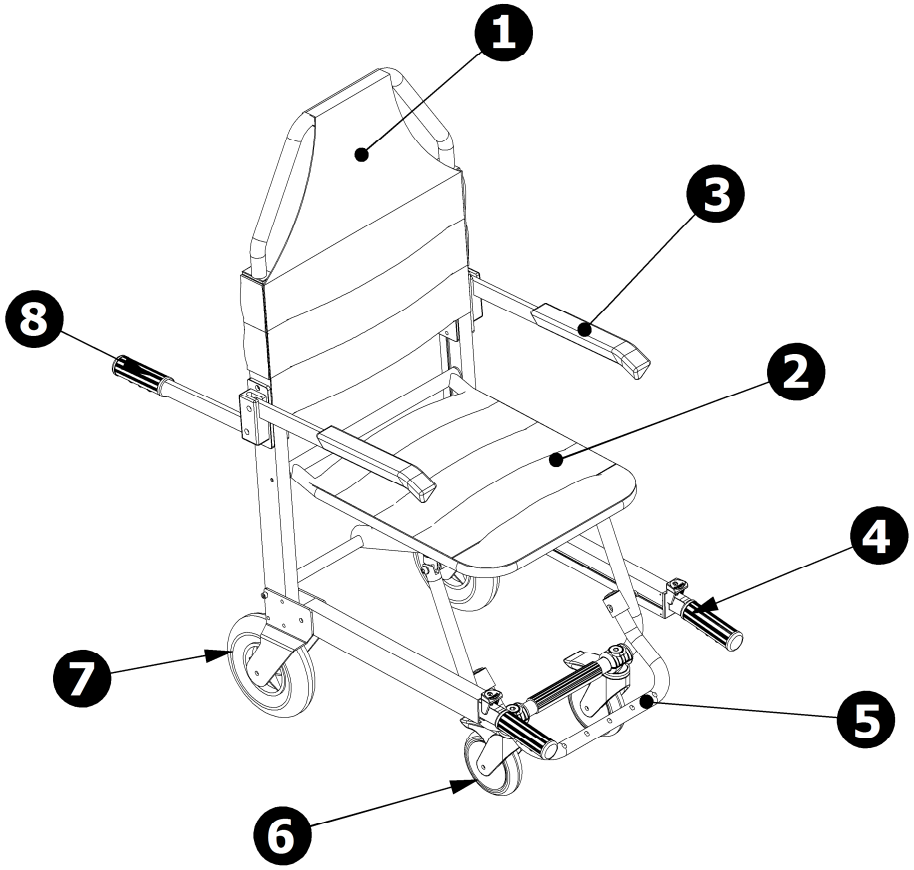

Fig. A

3.3 Models

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

ST10480A	Spencer 480

3.4 Technical data

Characteristics	Spencer 480
Length [mm]	550
Length open [mm]	750
Length extracted handles (mm)	1200
Height open [mm]	114
Tightness close [mm]	300
Weight [kg]	18
Load capacity [kg]	150

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 13485	Medical Devices - Managing systems for quality – Requirements for regulamentation requirements
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
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
UNI EN 1789	Medical vehicles and their equipment

3.6 Environmental conditions

Functioning temperature: from -15 to +50 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 15 to 90 %

4. OPERATING INSTRUCTIONS

4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.
During storage, do not place heavy materials over the device. The chair should not be considered and used as a shelf for any type of material.

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, straps, covers)
- Integrity of straps and covers
- Integrity of components
- Integrity of handles
- Lubrication of moving parts
- State of use of wheels and braking system
- Functioning of springs
- 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

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

4.3 Functioning

4.3.1 Opening the device

Grasp with one hand the backrest of the chair and use the other hand to unlock the piston by acting on the knob, pulling it towards you and keeping it in this position.
Accompany the descent of the seat until it is completely releasing the locking fixing knob.

4.3.2 Armrests

Lower the armrest in the functioning position, holding and pushing it downwards, until it reaches the parking position.
Similarly to close it again, the armrest must be raised and brought into the previous position.

4.3.3 Rear handles

Hold the rear handles lifting upwards until they reach the parking position.
Similarly to close the rear handles, they must be lowered and brought into the previous position.

4.3.4 Closing the device

Close the armrests and rear handles to avoid obstacles in the process of closing.
Grasp with one hand the backrest of the chair and use the other hand to unlock the piston by acting on the knob, pulling it towards you and keeping it in this position.
Lift the seat, bringing it vertically, release the fastening knob locking the chair in the closed position.

4.3.5 Telescopic handles

Take position in front of the device and grasp the pair of telescopic handles of the front part, moving them by pressing the button, obtaining in this way their complete output, locking them by releasing the button.
Also to bring them in the closed position, repeat the same procedure.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The device does not lock in the closed or open position during the opening or closing procedure	The functioning geometry is compromised or seized; the safety devices have not been removed	Ensure after proper lubrication if the problem persists. If so put the device out of service and contact the service centre.
Difficulties in the extraction and insertion of telescopic handles	Sediments in the sliding site or yielding of the aluminium profile	Carry out thorough cleaning. If the problem persists, do not use the device for handling involving the ascent of the stairs and call the service centre.
Damages to the structure	Misuse and inadequately trained staff	Put the device out of service and contact 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 following paragraphs.
All maintenance and revision activities must be traced and documented with their reports on technical intervention. The documentation must be kept for at least 10 years from the end of life of the product and must be made available to the competent authorities and/or the Manufacturer, when required.
With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations. In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users o any medical device.

5.3 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 month, 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, straps, covers)
- Integrity of straps and covers
- Integrity of components
- Integrity of handles
- Lubrication of moving parts
- State of use of wheels and braking system
- Functioning of springs
- 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 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 subjected to annual revisions to verify the proper operation and compliance with the safety requirements guaranteed by the Manufacturer when the device is placed on the market.
The revisions must be made by the Manufacturer, who uses specialized internal and external technicians and is authorized by the Manufacturer himself. In the absence of such annual revisions, the device must be SECRETED UNTIL REPAIRING, otherwise it must be DISPOSED OF AND IT MUST BE GIVEN COMMUNICATION TO THE MANUFACTURER.
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 Life span

The device, if used as described in this user manual, has an average life span of 5 years from the date of purchase, which can be extended following annual revisions.
The life span can be extended, based on manufacturer's or on authorized service center evaluation, if the safety requirements of the device are still guaranteed.
In the absence of such extensions, the device must be DISPOSED AND IT MUST BE COMMUNICATED TO THE MANUFACTURER.
Spencer Italia S.r.l. disclaims any responsibility for incorrect operation or for any damage caused by the use of devices not revised by the Manufacturer or authorized service center, or that have exceeded the maximum permissible life span.

5.2.4 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.

6. ACCESSORES AND SPARE PARTS

6.1 Accessories

There aren't any accessories for this product.

6.2 Spare parts

ST42021A	Black wheel Ø200 mm

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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