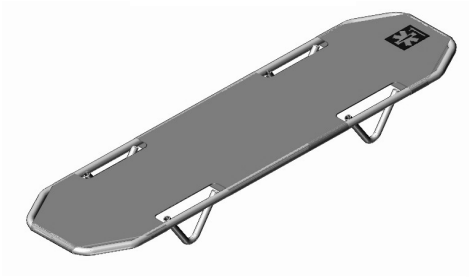
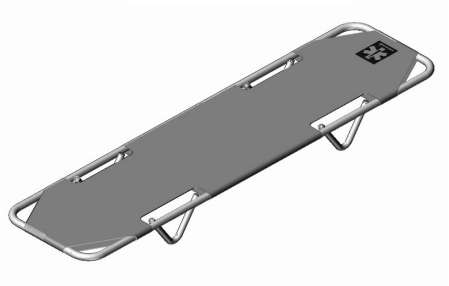
User Manual and Maintenance Handbook

Stock Series
Stacking Emergency Stretchers

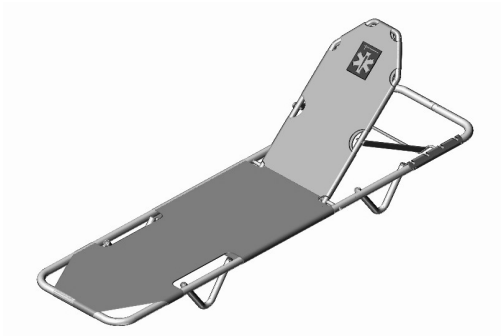
Spencer 270



Spencer 280



Spencer 281



Spencer 200

CE We declare that the device complies with the 93/42/EEC "Medical Devices" Directive.

Items produced and inspected under a Quality Management System certified by the notified body TÜV SÜD Product Service GmbH.

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Spencer Italia S.r.l. • Strada Cavi,7 • 43044 Collecchio (PR) ITALY
Tel. +39 0521.541111 • Fax +39 0521.541222 • E-mail: info@spencer.it
www.SPENCER.it

Thank you for choosing a Spencer product

1. GENERAL INFORMATION

1.1 Purpose and content

This manual is intended to provide the customer with all the necessary information so that, in addition to an appropriate use of the device, the user is able to manage the instrument in the most autonomous and the safest way possible. It includes information regarding the technical aspects, the functioning, the maintenance, spare parts and safety issues.

1.2 Preservation of the user manual

The user and maintenance manual must be kept for the entire life cycle of the device in use, nearby in the vicinity of the device, inside a special container and, above all, protected from any element or substance that could compromise its perfect readability.

1.3 Symbols used

Symbol	Meaning
	General and / or specific warnings
	Consult the relative instructions
LOT	Lot number
REF	Product identification code
CE	Product complies with the requirements of the 93/42/EC Directive

1.4 Request for assistance

For any information concerning the correct interpretation of the instructions, use, maintenance, installation, return, contact the Spencer Customer Service by calling 0039 0521 541111, or by fax at 0039 0521 541222, via e-mail info@spencer.it or write to Spencer Italia Srl—Cavi street, no.7—43044 Collecchio (Parma)—ITALY. In order to improve your customer service experience and to facilitate the assistance operations, always indicate or communicate the lot number (LOT) indicated on the label applied on the package or on the device itself.

1.5 Disposal

Once the devices reach their end-life and become unusable, if they have not been contaminated by special agents, they can be disposed of as normal municipal solid waste, otherwise their disposal must comply with the applicable regulations in force.

1.6 Labeling

Each device is equipped with a label, positioned on the device itself and / or on the packaging, in which the product's and Manufacturer's identification data appear, along with the CE marking and batch number (LOT). The label should never be removed nor covered.

2. WARNINGS

2.1 General warnings

- The product must only be used by previously trained personnel for handling this particular device and not other similar devices.
- The training must be recorded in a special register, where both the date and place of the training and the names of the participants and trainers are specified. This documentation, which will attest the operators' suitability for using the Spencer device, must be maintained for at least 10 years after the device's end of life and must be made available to the competent Authorities and / or to the Manufacturer when required.
- Spencer Italia Srl is always available for delivering training courses.
- Before carrying out any operation on the device (such as training, installation, use), the operators must carefully read the instructions contained in this publication, paying particular attention to the appropriate safety precautions and to the installation methods and operative instructions.
- In case that the operative instructions received with the device describe the operations for another device, different from the one received, it is mandatory to immediately contact the Manufacturer before using the device.
- In case of doubts regarding the correct interpretation of the instructions, please contact Spencer Italia Srl in order to obtain the necessary clarifications.

- Never allow untrained personnel to help while using this device as they may cause injury to the patient or to themselves.
- Carry out the prescribed maintenance and respect the average life time, as it is foreseen by the Manufacturer in the User Manual.
- Always check the integrity of the device before each use, as specified in the user manual. In case of anomalies or damage that could compromise the functionality and safety of the device, and therefore the patient's and the operator's safety, it is necessary to render it temporarily unavailable, isolate the device and contact the Manufacturer for support.
- If malfunctions are detected while using the device, it is necessary to replace it with a similar product right away, in order to guarantee the continuity of the rescue operations.
- It if forbidden to use the device for any other purpose different from what is described in this manual.
- Do not alter or arbitrarily modify the device; such modifications could cause unpredictable functioning and damage to patients or rescuers.
- The device must not undergo any tampering (modification, retouching, addition, repair), otherwise the Manufacturer will not be held responsible for the correct functioning or any damage caused by the device itself; moreover, in case of altering the device, the CE certification and product warranty become void.
- Anyone who modifies the device, or has it modified, or sets-up, or has it set-up in such a way that the devices no longer serves their intended purpose or no longer provide the expected performance must guarantee that the valid conditions for the first marketing are met.
- Handle with care.
- Make sure that you have taken every precaution to avoid hazards deriving from the contact with blood or with other body secretions.
- Register and store along with these instructions: the batch number, the place and date of purchase, date of first use, the checks' date, the users' name and comments.
- Assistance by qualified personnel must be guaranteed while using the device.
- Do not store the device under other, more or less heavy materials, which could damage the structure of the device.
- It must be stored in a dry, cool place, protected from light and must not be exposed to direct sunlight.
- Store and transport the device with its original packaging.
- The device must not be exposed to or come into contact with any combustion thermal sources and flammable agents.
- Position and adjust the device in such a way as not to hinder the rescuers' operations and the use of rescue equipment.
- Attention: despite all the efforts, laboratory tests, checks, operative instructions, the standards are not always able to reproduce the practice, so the results obtained in the real product's exploitation conditions in the natural environment may differ, sometimes also relevantly. The best instructions are the continuous practice under the supervision of competent and trained personnel.
- With reference to the Legislative Decree no. 46 of February 24th, 1997, amended with the Legislative Decree no. 37 of January 25th, 2010—the 93/42/EEC and 2007/47/EC Directive Transposition, it is recalled that public or private operators, who detect an incident involving a medical device in the exercise of their activity are required to notify the Ministry of Health, within the time frame and by the procedures established with one or more ministerial decrees, and the Manufacturer. Public or private health operators are required to notify the Manufacturer of any other inconvenience who may provide for the adoption of adequate measures in order to guarantee the patients' and users' protection and safety.
- As the Distributor or End User of the products manufactured and / or marketed by Spencer Italia Srl, it is strictly required to acknowledge the legal provisions in force within the goods' destination country, applicable to the devices that are being supplied (including the regulations concerning technical specifications and / or safety requirements) and, therefore, to know the necessary requirements in order to ensure compliance of these products with all the territory's legal requirements.
- Inform Spencer Italia S.r.l. promptly and in detail (already during the preliminary request phase) about any potential obligations due by the Manufacturer required in order for the products to comply with the territory's specific legal requirements (including those deriving from regulations and / or other normative provisions).
- Act, with due care and diligence, in order to help ensure compliance with the general safety requirements of devices that are placed on the market, providing end users with all the information required for them to be able to carry out the periodic testing activities on the fitted devices, exactly as indicated in the User Manual.
- Participate in the safety check of the products released on the market and transmitting the product's risks-related information to the Manufacturer and to the Competent Authorities in order for them to implement the necessary actions of their respective competence.
- Without prejudice to the foregoing, the Distributor or End User, shall assume as of now, the fullest accountability in relation to the failure to comply with the obligations indicated above, with the consequent obligation to keep Spencer Italia Srl unharmed and / or hold harmless from any possible detrimental effect.

2.2 Specific warnings

- Establish a maintenance program and periodic checks, by identifying a reference employee for this matter. The subject to whom the ordinary maintenance of the device is entrusted must guarantee the basic requirements described in these operative instructions by the Manufacturer.
- All maintenance and overhaul activities must be recorded and documented with the relative technical intervention reports (see Maintenance register). The documentation must be maintained for at least 10

years after the device's end of life and must be made available to the competent Authorities and / or of the Manufacturer, when requested.

- Use only original components / spare parts and / or accessories approved by Spencer Italia S.r.l., in order to be able to carry out any operation without causing alterations or modifications to the device; otherwise, the Manufacturer will not be held responsible for the correct functioning nor for any damage caused by the device to the patient or the operator, by invalidating the warranty and invalidating compliance with the 93/42/EEC Medical Devices Directive.
- Never leave the patients unattended when the device is in use, they may get injured.
- After being washed, the device must dry completely before being stored, away from direct sunlight and away from direct sources of heat.
- Avoid contact with sharp objects.
- Never use solvents or stain removers.
- The device should not be used in the presence of cuts, burns and abrasions.
- Avoid dragging the device on rough surfaces.
- Always check the integrity of the device before each use.
- In order to use the device, at least two operators in good physical conditions are required, according to the load to be moved.
- Always immobilize the patient, as failure to immobilize them can cause serious damage.
- Always respect the maximum carload prescribed.
- Distribute the weight correctly along the device.
- Before each use, check the correct tightening of the screws on the device.
- Follow the procedures approved by the Emergency Medical Service for positioning and transportation of the patient.
- The appropriate documentation required in order to trace the origin of the products must be stored for a period of ten years after transfer date towards the final consumer and, therefore, rendered available, where required.

2.3 Contraindications and side effects

The use of this device does not present any contraindications or side effects, if operated and used as described within this user manual.

2.4 Physical requirements for the operators

The folding stretchers are devices intended exclusively for professional use. Operators using them must have the following minimum requirements:

- physical ability to use the device
- must be able to grasp the device firmly with both hands
- present strong back, arms and legs to lift and support it
- have good muscle coordination

Each operator must be adequately trained to transport patients safely and efficiently.
Loading techniques, in case of particularly heavy patients or in the presence of steep terrain and unusual situations, may require the deployment of more than two operators.

The abilities of each operator must be fairly evaluated before defining the roles of the rescuers for using the device.

3. PRODUCT DESCRIPTION

3.1 Intended use

The Stock Series emergency folding stretchers are devices designed to transport the patient in a relaxed position.

3.2 Main components

1. Steel anchorage feet
2. Backrest adjustment rack
3. Backrest adjustment bars
4. Adjustable backrest
5. Spentex® clothing
6. Treated aluminum frame

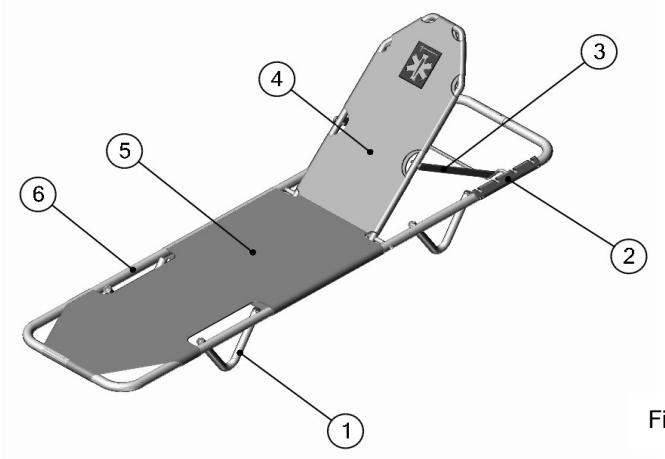


Fig. A

3.3 Models

The following basic models may be subjected to code and/or description related changes, without prior notice.

Series 270
ST00270A—SPENCER 270 YELLOW STACKING EMERGENCY STRETCHER
ST30270A—SPENCER 270 ORANGE STACKING EMERGENCY STRETCHER
ST10270A—SPENCER 270 MILITARY STACKING EMERGENCY STRETCHER
ST20270A—SPENCER 270 BLUE STACKING EMERGENCY STRETCHER
ST40270B—SPENCER 270 STACKING EMERGENCY STRETCHER FOR DECONTAMINATION

Series 280
ST00280A—SPENCER 280 YELLOW STACKING EMERGENCY STRETCHER
ST30280A—SPENCER 280 ORANGE STACKING EMERGENCY STRETCHER
ST10280A—SPENCER 280 MILITARY STACKING EMERGENCY STRETCHER
ST20280A—SPENCER 280 BLUE STACKING EMERGENCY STRETCHER

Series 281
ST00281A—SPENCER 281 YELLOW STACKING EMERGENCY STRETCHER WITH HEADREST
ST30281A—SPENCER 281 ORANGE STACKING EMERGENCY STRETCHER WITH HEADREST
ST10281A—SPENCER 281 MILITARY STACKING EMERGENCY STRETCHER WITH HEADREST
ST20281A—SPENCER 281 BLUE STACKING EMERGENCY STRETCHER WITH HEADREST

3.4 Technical data

	Spencer 270	Spencer 280	Spencer 281
Length opened (mm)	1885	1885	1885
Width (mm)	475	475	475
Height (mm)	175	175	175
Weight (kg)	5	5	6
Carload (kg)	170	170	170
Gripping points (n°)	8	8	6
Anchorage feet (n°)	4	4	4

3.5 Reference standards

Reference	Document Title
MDD 93/42/EEC	European Directive concerning Medical Devices
MDD 2007/47/EEC	Amendment to the 90/385/EEC Directive on active implantable, the 93/42/EEC Directive on medical devices and the 98/8/EC Directive concerning the placing of biocidal products on the market.
Legislative Decree no. 46 of February 24th, 1997	Implementation of the 93/42/EEC Directive, concerning Medical Devices
Legislative Decree no. 35 of January 1st, 2010	Amendments and additions to the Legislative Decree no. 46 of February 24th, 1997
UNI EN ISO 9001	Quality management systems: requirements
UNI EN ISO 9000	Quality management systems—Fundamentals and vocabulary
UNI EN ISO 13485	Medical devices—Quality management systems—Requirements for regulatory purposes
UNI EN ISO 14971	Application of risk management to medical devices
UNI CEI EN 980	Symbols For Use In The Labeling Of Medical Devices
UNI CEI EN 1041	Information Supplied By The Manufacturer Of Medical Devices
CEI EN 62366	Medical devices—Application of usability engineering to medical devices
MEDDEV 2.4 / 1a-b	Guidelines 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 investigation of medical devices for human subjects — Part 2: Clinical investigation plans
BS OHSAS 18001	Occupational Health and Safety

3.6 Environmental conditions

Temperature of use: from -20° C to +60 ° C
Storage temperature: from -20° C to +60 ° C
Relative humidity: from 20% up to 80%

4. OPERATIVE INSTRUCTIONS

4.1 Transportation and storage

Before transporting the device, make sure that it has been packed properly and undertook all efforts in such a way that there is no falling or collision risk during transport. Keep the original packaging for any subsequent transport and storage.

Damage caused during transport and handling are not covered by warranty. Repairs or replacements of damaged parts are the customer's responsibility.

The device must be stored in a dry, cool place, away from light and sun. It must not come into contact with ignition sources, flammable agents and / or substances, nor with chemical agents, which could alter its safety features.

4.2 Preparation

Upon receipt of the product:

- Remove the packaging and arrange the material in a visible way.
- Check that all the pieces included in the accompanying list are present.

The device must be checked before each start-up, so as to detect malfunctions and / or damage due to transport and / or storage. In particular check:

- Overall functionality of the device
- Device cleaning status (please note that failure to perform cleaning operations may result in a risk of cross-infection)
- Absence of cuts, burns and abrasions on the whole structure
- Wear state
- Check the quick release belts for presence and correct fastening to (Fig. B)

Fig. B

If the reported conditions are met, the device can be considered ready for use; otherwise it is necessary to immediately isolate the device and contact the Manufacturer.

4.3 Modus operandi

4.3.1 Backrest adjustment (only for Spencer 281)

Fig. C

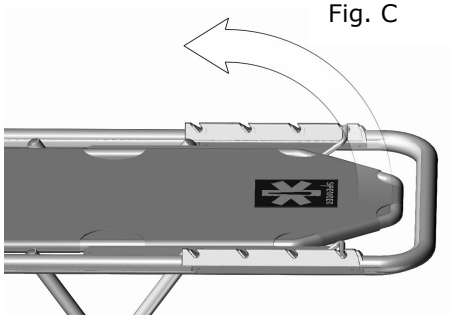


Fig. D

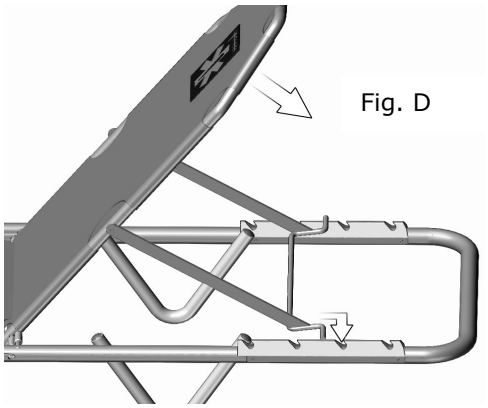
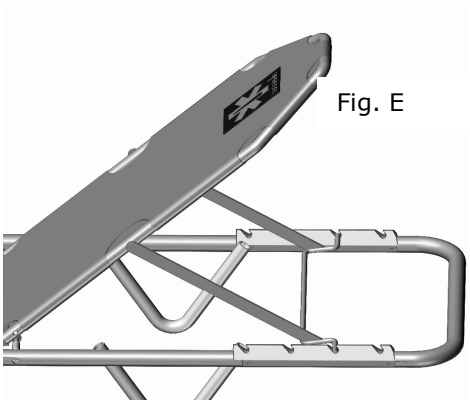


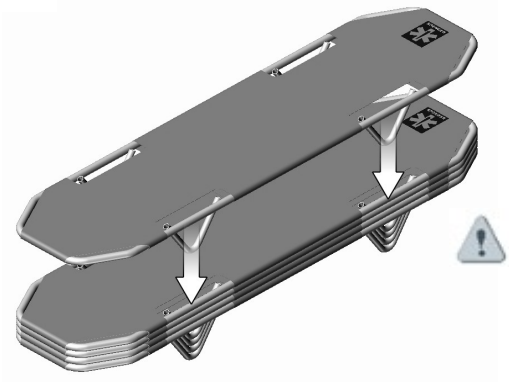
Fig. E



1. Lift the backrest by acting upon the head side as shown in Fig. C and bring it to the desired inclination.
2. Make sure that the adjustment bars are in contact with the rack, and then accompany the descending of the backrest (Fig.D) until the special pins are hooked into the rack seats (Fig. E)

Fig. F

2 Overlapping storage

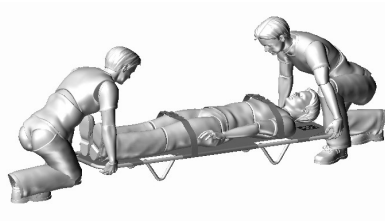


Overlap the stretchers neatly, making sure you let the anchorage feet of the stretcher that you wish to stack, inside the appropriate slots of the stretcher below.

It is recommended to overlap an adequate number of stretchers such that each rescuer can easily reach the highest position.

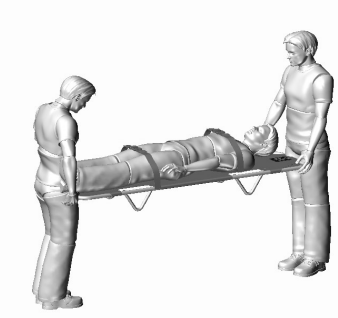
4.3.3 Placing the patient on the stretcher

1 Place the device on the ground, and make sure it is stable.
2 Position the patient, paying special attention to respecting the medical provisions according to the patient's health state and considering the traumas suffered.
3 Secure the patient with the quick release belts.



4.3.4 Lifting the stretcher with patient

1 The operators should be positioned towards each end of the stretcher.
2 Using the appropriate lifting technique, to avoid fatigue, workers must grasp the respective handles. Asses the deployment of either two or more operators, based on the load on the device.



If the environmental conditions, or other external elements, make transport operations problematic, the presence of several operators is recommended.

4.4 BREAKDOWN MANAGEMENT TABLE

PROBLEM	CAUSE	SOLUTION
The stretcher is not stable	Supporting structure damaged	Immediately take the device out of service and contact the Customer Support Center.
	Anchorage feet damaged	Immediately take the device out of service and contact the Customer Support Center.
Faulty closures	Junctions damaged	Immediately take the device out of service and contact the Customer Support Center.
Clothing is not sufficiently rigid	Tear or broken welds	Immediately take the device out of service and contact the Customer Support Center.

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Failing to perform the cleaning operations may result in the risk of cross-infection due to the presence of secretions and / or residues.

During all control and sanitation operations, the operator must wear adequate personal protective equipment, such as gloves, glasses, etc.

Wash exposed parts with lukewarm water and neutral soap; never use solvents or stain removers.
In case of possible disinfection, use solvent free products with no corrosive action on all materials constituting the device.
Rinse thoroughly with lukewarm water, making sure to remove all traces of detergent, as they could deteriorate or compromise its integrity and durability.
Allow it to dry perfectly before storing the device. After washing or using the device in a humid environment the drying must be natural and not forced; do not use flames or other sources of direct heat.

5.2 Maintenance

5.2.1 Ordinary maintenance

The subject to whom the ordinary maintenance of the device is entrusted to must guarantee the following basic requirements:

- Technical knowledge of the device, of the periodic maintenance operations established within these instructions.
- Use of technical personnel with specific qualifications, education and training for the maintenance operations to be performed on the device in question.
- Use of original / approved components / parts or accessory materials (if provided), in order to carry out any operation without altering or modifying the device.
- Possession of control and verification systems relevant for the operations performed on the device.
- Ensure full compliance with the requirements of the 93/42/EEC Directive also with regard to the obligations towards the Manufacturer that require to allow him the post-sales surveillance and traceability of the devices, at all times.

During all inspection, maintenance and sanitation operations, the operator must wear appropriate personal protective equipment, such as gloves, goggles, etc.

The checks which must be carried out before and after each commissioning, and at least every 3 months, are described as follows:

- Overall functionality of the device and of the belts
- Device cleaning status (please note that failure to perform cleaning operations may result in a risk of cross-infection)
- Absence of cuts, burns and abrasions on the whole structure
- Wear state

The checks' frequency is determined by factors such as legal requirements, type of use, frequency of use, environmental conditions during use and storage conditions. Remember that the cleaning described in paragraph 5.1 and the functionality check must be performed before and after each commissioning. Spencer Italia S.r.l. declines all responsibility for the correct functioning or for any damage caused to the patient or to the operator while using devices not subjected to routine maintenance, invalidating warranty and also invalidating the compliance with the 93/42/EEC Medical Devices Directive.

5.2.2 Regular revision

No scheduled periodic maintenance is required at the Manufacturer or within centers authorized by him, but the cleaning and checks indicated in the "Cleaning" and "Ordinary Maintenance" paragraphs are mandatory as prescribed.

5.2.3 Extraordinary maintenance

Extraordinary maintenance can only be performed by the Manufacturer or within centers authorized by the Manufacturer.

We remind you that in case of interventions performed not by the Manufacturer, but by an authorized center, it is necessary to request a report on the activity performed. This will allow both Spencer Italia S.r.l. and the user to track all the interventions performed over time.

The device, if used as reported in the following instructions, has an average life time of 5 years.

The life time can be extended only after a general revision carried out by the Manufacturer or within a center authorized by the manufacturer.

Spencer Italia S.r.l. declines all responsibility for the correct functioning or for any damage caused by the use of repaired devices, or devices that have been certified as at the end of their life time elsewhere, but not by the Manufacturer or by centers authorized by the Manufacturer, invalidating the warranty and invalidating the compliance to 93/42/EEC Medical Devices Directive.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

There are no accessories prescribed for this product

6.2 Spare Parts

There are no spare parts prescribed for this product