User's Manual

ENERGY
Heat regulating bag for IV liquid warming

CE 0123 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

First edition: 20/12/00
Rev. 12: 25/06/18

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
SN	Serial number
REF	Product code
CE 0123	The product is compliant with the specifications of the Directive 93/42/CEE
	Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding Reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes.
	Fuse
12 V DC	Rated voltage supplies
	Isolation class II

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

Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes".

The crossed dustbin symbol applied on the product or on its packaging indicates that the item should be disposed of separately.

The correct disposal of the item when use has terminated, is defined and organised by the manufacturer. The end user, who has to proceed with disposal, must therefore contact the manufacturer and follow the system and procedures the manufacturer has organised for the separate collection, treatment and disposal at end-of-life.

The correct separate collection of the out of use device which will permit recycling, treatment and destruction in an ecologically friendly manner and will contribute to avoiding possible negative effects on the environment and for health while privileging the reuse and/or re-cycling of the collected waste components.

Please note that the owner will be subject to administrative sanctions in case of unauthorised disposal of the item.

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 lot number (LOT) or the serial number (SN). It must never be removed or covered.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- 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.
- Do not use the device if it eccessively worn out.
- Avoid pulling the device on rough surfaces.
- Use the device only as described in this user's manual.
- This product can used only by trained medical staff.
- Before connecting the device, check that the electrical circuit of the sanitary vehicle is conform and compatible with the connections of Energy.
- The operating temperature of the bag 38 °C ±4 °C will be obtained in about 7 minutes (at a room temperature of 18 °C ±3 °C), after inserting the connection into the emergency vehicle.
- The time required to reach the ideal temperature depends on the initial temperature of the IV liquid, on the external temperature, on the chemical composition of the liquid, on the IV container and on the time that the device is connected to the power source of the ambulance.
- During use the Energy bag must be kept in the upright vertical position.
- The use of the device in atmospheric conditions other than those indicated, could compromise the safety of the device.
- **Energy is a heat regulating bag for the warming of IV liquids and must never be used to warm blood or plasma.**
- **Special precautions regarding EMC (electromagnetic compatability) must be taken before using this device and the device must be conform to all the specifications regarding the EMC conformity contained within this manual.**
- **Radio communication devices (fixed and mobile) could influence the correct functioning of the device.**
- **The device can be used for a maximum of 48 consecutive hours and no further.**

2.3 Contraindications and side effects

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

3. DESCRIPTION OF PRODUCT

3.1 Intended use

Energy is a heat regulating bag for the warming of IV liquids. The use of the device as an active source of heat is indicated for the prevention and treatment of hypothermia. It is an ideal thermal container for emergency medicine services but can also be used in hospitals, field camps or mountain areas. It is compact and can be used both hung on the stretcher or in the ambulance as a bottle holder or inside other bigger containers.
Thanks to this bag, the infusion liquids remain at a constant temperature and the IV liquids can be transported out of the ambulance for a short period.

3.2 Main components

The heating pouch has a front pocket for the electric power supply cable, a transparent identity pocket for the logo, a cable with plug and adjustable shoulder strap.

3.3 Models

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

IF03030A Energy

3.4 Technical data

Length	250 mm
Width	140 mm
Height	330 mm
Weight	1,2 kg
Material and outside padding	PVC
Inside padding	nylon 210
Rated voltage supplies	12 V DC
Internal carabiners	n° 2 in nylon 66
Source of heat	ultra-thin resistance in metal alloy
Rated power[NOTE]	45 W at 12V (higher tension should result in increased absorption)
Absorption	3,75 A
Fuses	7,5 A lamellar 32V brown, in the cigarette lighter plug
Cigarette lighter	DIN ISO 4165
Thermostat	n° 3
IP degrees of protection	IP3x
Isolation class	II

NOTE: To ensure a power consuption as stated in the details above, the installer shall adopt a voltage stabilizer with an output between 4 and 5A

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 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
CEI EN 60601-1 (CEI 62-5) and all ones recalled	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
CEI EN 60601-1-2	Medcal electrical equipment. Part 1: Medical electrical equipment. Part 1: General requirements for safety. Collateral standard: Electromagnetic compatibility.
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

3.6 Environmental conditions

Functioning temperature: from -20 to +40 °C

Storage temperature: from -20 to +50 °C
Relative humidity: from 30 to 70%

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
- Integrity of components (power cable and plug)
- Connection to a power supply of 12 V DC
- Integrity of fuse
- Integrity of internal carabiners
- Correct functioning of zippers

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

Remember that the plug of the device must be inserted in the power source of the vehicle and please note that:

- **It takes about 7 minutes at a room temperature of 18 °C ±3 °C to obtain the correct temperature of the bag (38 °C ±4 °C).**
- **The time necessary for the infusion liquid to reach the temperature, depends on the initial temperature of the liquid, on the external temperature, on the chemical composition of the liquid and on the characteristics of the liquid container.**

1. Disconnect the plug from the power.
2. Wind up the cable, put it inside the front pouch and close the zip.
3. Open the zip of the main compartment for the IV liquid and position the IV bag using the carabiner clips.
4. Open the buttonhole in the base of the bag and thread the connectors towards the outside. Following this close the buttonhole with the eyelet
5. Close the zip of the bag and proceed with the patient.
6. Make sure that the ENERGY bag is in the vertical position and that it is properly connected to the means of transport and in a position which is not prone to accidental bumps and bangs. We advise the use of the E-tube isolation tube (IF03031A) which wraps round the exit tube of the IV solution.

The device requires some particular attention regarding the EMC (electromagnetic compatibility) and should be used in conformity to the EMC information contained in this user's manual.
The use of portable and mobile radio systems may influence the functioning of the device.

Warning: RF equipment can cause improper operation of the device (wrong temperature measuring). Do no use RF equipment at a dinstance less than 30cm from the device or its components.

Guide and Manufacturer's Declaration		
Energy is intended for use in the electromagnetic environment specified below. The customer or the user of Energy must ensure that it is used in such an environment.		
EMISSION TESTS	**Conformity**	**Guide to the electromagnetic environment**
Emissions in RF CISPR 11	Group 1	The Energy uses RF energy only for its internal functions. Its RF emissions are therefore very low and unlikely to cause any interference with electronic equipment nearby.
Emissions in RF CISPR 11	Class B	The Energy is suitable for use in all environments including domestic as well as those directly connected to a low-voltage public network source supply of which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2		
Emissions as a result of voltage fluctuations / flicker-IEC 6100 3-3	Compliant	

Guide and Manufacturer's Declaration		
The Energy is intended for use in the electromagnetic environment specified below. The customer and / or user of the Energy must ensure that the device is used in such environment.		
IMMUNITY TEST	**Conformity level**	**Guida all'ambiente elettromagnetico**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV at contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	I Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should not exceed most 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV power supply ± 1kV for input/ouput lines	Mains power quality should be that of a typical commercial or hospital environment.
Over voltage IEC 61000-4-5	± 0.5 , 1kV for line to line surge 0.5, 1, 2kV for line to ground surge	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycles at 0°, 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT 1 cycle and 70% UT 25/30 cycles (25 at 50Hz and 30 at 60Hz) Single phase ta 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Energy requires continued operation during power mains interruptions, it is recommended that the Energy be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
note UT is the value of the tension of power source		

Guide and Manufacturer's Declaration		
Energy is intended for use in the electromagnetic environment specified below. The customer and / or end user of Energy must ensure that the equipment is used in such environment.		
IMMUNITY TEST	**Level of conformity**	**Guide to the electromagnetic environment**
Conducted RF IEC 61000-4-6	6 V 150kHz to 80MHz in ISM bands and amateur radio bands	The equipment for communication in portable and mobile radio-frequency (RF) should not be placed near any part of the appliance, including cables etc. and should be kept at a distance never less than the recommended and calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 0{,}583x\sqrt{P}$
	80% AM a 1khz	$d = 1{,}2\ x\sqrt{P}$ from 80Mhz to 800MHz
Radiated immunity CEI EN 61000-4-3	10 V/m 80MHz to 2.7 Ghz	$d = 2{,}3\ x\sqrt{P}$ from 800Mhz to 2,7 GHz where P is the maximum rated power output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be at less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz the separation distance for the range of higher frequency is applied		

NOTA 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Energy is used exceeds the applicable RF compliance level above, the Energy should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Energy.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Recommended separation distances between portable and mobile communications equipment and Energy.

The Energy is intended for use in an electromagnetic environment in which radiated RF disturbance is controlled. The customer or the user of the Energy may prevent electromagnetic interference by maintaining a minimum distance between the communications equipment radio frequency (RF) Portable and mobile equipment (transmitters) and the Energy, as described below and in accordance with the maximum output power of the communication device

Maximum output power rating of the transmitter	Separation distances according to frequency of transmitter (m)		
(W)	From 150 kHz to 80 Mhz Inside and outside ISM bands $d = 0{,}583x\sqrt{P}$	From 80 Mhz to 800 Mhz $d = 1{,}2x\sqrt{P}$	From 800 Mhz to 2,7 Ghz $d = 2{,}3x\sqrt{P}$
0,01	0.058	0,12	0.23
0,1	0.184	0,38	0.73
1	0.583	1,2	2.3
10	1.844	3,8	7,3
100	5.83	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guide and Manufacturer's Declaration

Immunity to proximity fields from RF wireless communications equipment

Frequenza di test (MHz)	**Modulation**	**Immunity level (V/m)**
385	Pulse modulation[(1)] at 18Hz	27
450	FM[(2)] ±5Hz deviation 1kHz sine	28
710	Pulse modulation[(1)] at 217Hz	9
745	Pulse modulation[(1)] at 217Hz	9
780	Pulse modulation[(1)] at 217Hz	9
810	Pulse modulation[(1)] at 18Hz	28
870	Pulse modulation[(1)] at 18Hz	28
930	Pulse modulation[(1)] at 18Hz	28
1720	Pulse modulation[(1)] at 217Hz	28
1845	Pulse modulation[(1)] at 217Hz	28
1970	Pulse modulation[(1)] at 217Hz	28
2450	Pulse modulation[(1)] at 217Hz	28
5240	Pulse modulation[(1)] at 217Hz	9
5500	Pulse modulation[(1)] at 217Hz	9
5785	Pulse modulation[(1)] at 217Hz	9

The carrier shall be modulated using a 50 % duty cycle square wave signal.

As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Energy is not heating up	The source of power and Energy are not compatible	Check that the source of power of the emergency vehicle is compatible with that of the Energy
	No contact between the plug and the socket of the 12 V DC of the emergency vehicle	Make sure that the metal elements of the plug come into contact with the socket correctly
	Interruption of power source between emergency vehicle and device	Un-attach the cable and check the state of it. If it results damaged, the device must be put out of service and the Spencer Customer service contacted.
	The battery of the emergency vehicle has gone flat	Check that the power source has been correctly loaded and if necessary re-load

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.

Before completing any cleaning operations on the device, make sure that all electrical components (cable, plug) are adequately protected.

For correct storage carry out the following routine operations.

Clean the outside and the inside with a clean cloth using any type of disinfect on the market (bactericidal, germicidal); with a clean damp cloth removing all residuals of the disinfectant and 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 (in order to make this check, the device should be attached to the power source of the emergency vehicle and after about 3 minutes on inserting your hand inside the bag you will feel that the warming process is proceeding)
- 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
- Integrity of components (power cable and plug)
- Connection to a power supply of 12 V DC
- Integrity of fuse
- Integrity of internal carabiners
- Correct functioning of zippers

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 above mentioned revision is not carried out the conformity to the Directive 93/42/CE for medical devices will no longer be valid therefore, even though the CE mark if present, it is possible that the device no longer answers all the requirements as indicated by the Manufacturer at purchase.

Spencer Italia S.r.l. will take no responsibility the incorrect functioning or any damage caused by a device that has not undergone regular revision.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

5.2.3 Special servicing

Only the Manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded up to another 5 years only following a general revision of the product that must be carried out by the Manufacturer or by a centre authorised by the Manufacturer every year.

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

IF03031A E-tube isolating tube

6.2 Spare parts

There aren't any spare parts for this device.