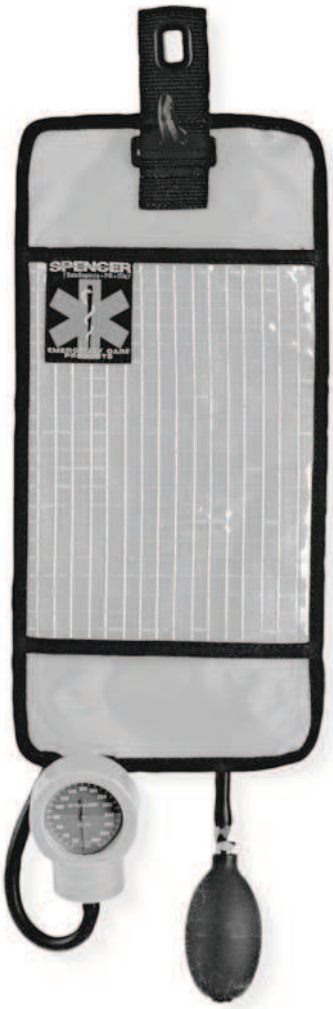
SPENCER®

User's Manual

# WIV / Air WIV
## IV subministration bags



**WIV**

**Air WIV**

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

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

## INDEX




First edition: 26/09/05
Rev. 3: 05/07/12



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**Thank you for choosing a Spencer product**

# 1. GENERAL INFORMATION

## 1.1 Aim and contents

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

## 1.2 Conservation of the instruction manual

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

## 1.3 Symbols used

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

## 1.4 Servicing requests

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

## 1.5 Demolition

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

## 1.6 Labelling

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

# 2. WARNINGS

## 2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the Manufacturer in this User's Manual.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Use of the device in anyway other than described in this manual is forbidden.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Handle with care.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.

- When the device is being used, the assistance of qualified staff must be guaranteed.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
  In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users of any medical device.
- As a Distributor or End Users of products manufactured and/or marketed by Spencer Italia S.r.l., you are strictly required to have a basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the goods final destination Country (including laws and norms regarding technical specifications and / or safety requirements) and therefore you are also strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.
- Promptly notify Spencer Italia S.r.l. regarding any revisions to be made by Manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, as specified in the relevant User Manual.
- Actively contribute to product safety checks on products sold, by communicating any relevant risk analysis information both to the Manufacturer and to any competent authorities so that the necessary action can be promptly taken.
- You are aware that in the event of any failure to conform to the above mentioned requirements you will be deemed fully responsible for all damages that might occur. Therefore we expressly disclaim any responsibility and/or liability for your non-compliance with the present "Regulatory provisions".

### 2.2 Specific warnings

- 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.
- 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.
- 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.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport device in its original packaging.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Use only with 500 and 1000 ml IV subministration bags.
- Before each use check that the needle of the pressure gauge indicates zero.
- After use open the air valve on the pump so that the needle of the pressure gauge indicates zero.
- Do not exceed the maximum pressure allowed, the device may be damaged.

### 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

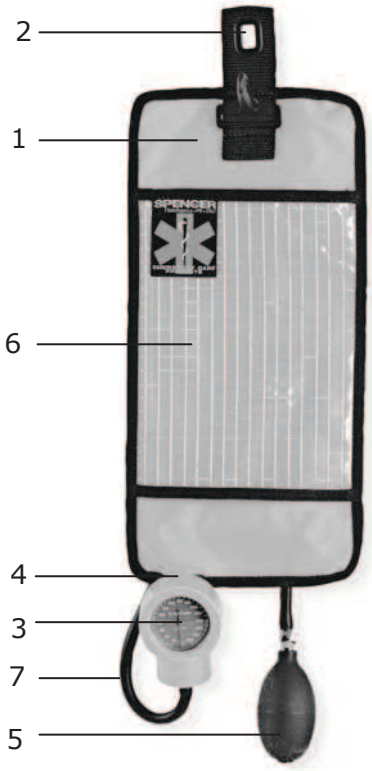
### 3.1 Intended use

The devices have been made for IV infusion treatments. The WIV and AIR WIV IV subministration bags have been studied for containing bags or IV infusions which can be squeezed thanks to the air chamber activated by a pump. They are intended for use during the transportation of the patient, but can also be usefully employed in hospitals, clinics and medical surgeries. The devices can be reused.

### 3.2 Main components

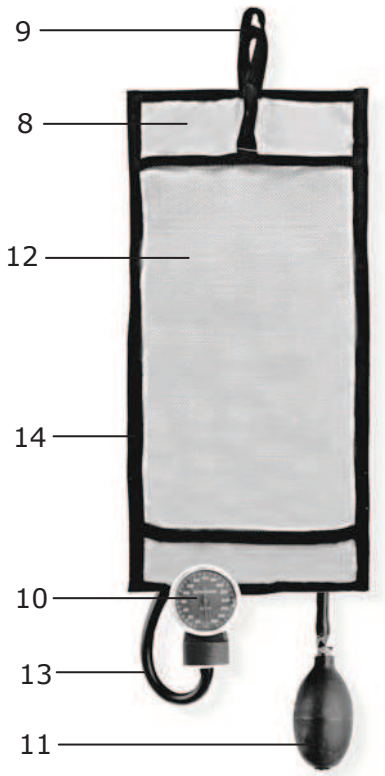
#### 3.2.1 Main components WIV

1 Polyurethane cover obtained by HFW
2 Ring for fast attachment
3 Manometer
4 Cover for pressure gauge in elastic and shockproof rubber
5 Pump with deflating valve
6 PVC frontal window with nylon weft
7 Rubber tubes




#### 3.2.2 Main components Air WIV

8 Nylon cover
9 Carabiner clip for fast attachment
10 Manometer
11 Pump with deflating valve
12 PVC frontal window
13 Rubber tubes
14 Air chamber in rubber




### 3.3 Models

IF00301A WIV IV subministration bag
IF00310B Air WIV IV subministration bag with air chamber

### 3.4 Technical data

| Characteristics | WIV | Air WIV |
|---|---|---|
| Dimension | 250 x 15 x h375mm | 170 x 15 x h380 mm |
| Weight | 200 g | 300 g |
| Materials | Nylon, PVC, rubber | Nylon, PVC, rubber |
| Ring for attachment | X | X |
| Air chamber | X | X |
| Cover for pressure gauge | X | - |
| Maximum pressure | 250 mmHg | 250 mmHg |

### 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 |
| 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 0 to +40 °C
Storage temperature: from -10 to +50 °C
Relative humidity: from 5 to 95%

## 4. OPERATING INSTRUCTIONS

### 4.1 Transport and storage

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

### 4.2 Preparation

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.

### 4.3 Functioning

1- Insert the IV infusion inside the device. An eyelet placed in the upper part allows the IV subministration bag to be hung up.
2- Compress repeatedly the pump until the pressure required is reached on the pressure gauge, graduated in millimetres of mercury (mmHg).
3- To vary the pressure of the IV subministration bag operate either on the pump (to increase the pressure) or on the air valve (to reduce the pressure).

**Before each use check that the needle of the pressure gauge indicates zero.**
**After use open the air valve on the pump so that the needle of the pressure gauge indicates zero.**

### 4.4 Troubleshooting

| PROBLEM | CAUSE | REMEDY |
|---|---|---|
| The device does not inflate | The deflating valve is open | Close the deflating valve on the pump |
| The device deflates | Possible leak of air | Immediately put the device out of service and contact the service centre |

## 5. MAINTENANCE AND CLEANING

### 5.1 Cleaning

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

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

The IV subministration bag must not be immersed into water. After use, check the cleanliness of the appliance and when necessary, clean the covering of the infusion pump with a damp sponge (use only a mild detergent and water). Avoid use of solvents and stain removers. For disinfection, use only products that have not corrosive or solvent action on the materials of the device.
Make sure to eliminate all traces of detergent, which might damage or compromise the integrity and durability of the device.
Allow to dry thoroughly before storing. Drying after washing or after use in wet environments must be natural and not forced, do not use flames or other sources of direct heat.

### 5.2 Maintenance

#### 5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

**During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.**

Checks to be carried out before and after each use, and at least every 3 months, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Presence of cuts, holes, abrasions
- Integrity of pump
- Pump seal
- Integrity and functionality of manometer

**The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage.** Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance warranty and will void the compliance to the Medical Device Directive 93/42/CEE.
The person responsible for routine maintenance can identify damaged/worn parts, but the replacement or restoration of the them can only be done by the manufacturer or or by an authorized service center.

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 does not require periodic maintenance by the manufacturer, however, the routine maintenance must be guaranteed as indicated on paargraph 5.2.1

### 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.

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

There are no accessories or replacement parts for this device.

**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 | | |
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**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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