


User's Manual

FL-X Flowmeter



 **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

| | |
|------------------------|---------|
| General information | page 14 |
| Warnings | page 14 |
| Description of product | page 17 |

| | |
|-----------------------------|---------|
| Operating instructions | page 18 |
| Maintenance and cleaning | page 19 |
| Accessories and spare parts | page 22 |

First edition: 18/04/09
Rev. 2: 30/05/11

1. GENERAL INFORMATION








1.1 Aim and contents

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

1.2 Conservation of the instruction manual

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

1.3 Symbols used

| Symbol | Meaning |
|---|---|
|  | General or specific warning |
|  | See instructions for use |
|  | Lot number |
|  | Product code |
|  | The product is compliant with the specifications of the Directive 93/42/CEE |
|  | Do not use lubricants |
|  | Oxygen |

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

Follow the current regulations.

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 available for conducting training courses.
- 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 personnel to help when using the device as they may cause injury to the patient or themselves.
- Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the 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.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- 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.



2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying an 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.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Connection of the flowmeter to a pressure reducer should be done only by staff who have been adequately trained for this specific operation.
- Check for the absence of any lubricants, oil or grease or potentially inflammable substances on the connection thread. If they are found or even just suspected, the device should not be used.
- Do not alter the safety valve.
- The connecting tubes must conform to the EN ISO 5359 norm.
- Before using this device, make sure that the pressure reducer is branded for the same type of gas as indicated on the cylinder and on the flowmeter.
- Keep the device in the vertical position during use. Accuracy can be guaranteed only in the vertical position.
- Any leakage could reduce accuracy.
- The adjusting tap must always be closed when the device is not in use.
- Over tightening could cause damage to the needle of the flow adjustment tap which could consequently cause problems with the flow supply.
- The device must be transported and stored under the temperature conditions specified by the manufacturer. Failure to do so could compromise the correct functioning of the device.
- Replacement of device attachments for measuring the flow rate could compromise the functioning and safety of the product.
- Variation of the inlet pressure and of the resistance of the outlet pressure could reduce the accuracy of flow.
- Temperature variations between 0 and +40 °C could reduce accuracy of the flow.
- Do not disassemble the flowmeter when under pressure.
- None of the components of the flowmeter should be lubricated. **The use of lubricants could cause fire or explosions.**
- If the flowmeter is connected to a humidifier, it should be filled ONLY with distilled water in order to prevent presence of limestone and oxidation of the flowmeter.

2.2.1 ADDITIONAL WARNINGS, SPECIFICATIONS IN CASE OF USE WITH OXYGEN

- Only properly labelled cylinders must be used. There should be no doubt regarding the type of gas, the loading pressure and the good condition of the cylinder.
- The cylinder in use should be blocked in the correct position (ex. on a trolley with a chain).
- If any disfunctions or anomalies such as general leakages from the safety valve, strange noises, irregular manometer function, unstable exit pressure, excessive gas consumption are noted the product must be immediately removed from service and Spencer assistance centre should be contact.
- Replacement of O ring is not permitted.
- Do not use in the presence of flames or near sources of heat.
- Cylinders that have been exposed to the direct sun or near sources of heat must not be used.
- Careful attention must be paid to the integrity and cleaning of all connections and of the device in general.
- Any maintenance should be done with the devices removed from the cylinders of medical gas supply.

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 Spencer flowmeter can be used in the distribution of medical gases and is particularly adapt for being assembling with medical gas reducers as requested by the existing norms regarding connection to gas cylinders and actual norms. It may be connected to the inlets in accordance with the standards used in the final user's Country.

3.2 Main components

The main chromed components of the flowmeter are manufactured with anodized aluminium. The device has got a safety valve which will release at a safety pressure, it should in no way be tampered with.

The main components are:

- adjustment tap with needle for the correct dosage of the gas flow for the therapy being given
- main body in which the main components for the measurement of gas are located
- flowmeter tube with graduated scale, complete with float to indicate the flow supply
- indicator
- external cover
- supply connection
- medical gas exit connection

3.3 Models

| | |
|-----------------|---|
| FL08320C | FL-X FLUSSIMETRO WITH UNI INLET AND INLET Ø 7 |
| FL08321C | FL-X FLUSSIMETRO WITH AFNOR INLET AND INLET Ø 7 |
| FL08322C | FL-X FLUSSIMETRO WITH DIN INLET AND INLET Ø 7 |

These basic models could be modified, with reference to codes and/or descriptions without any previous advice.

3.4 Technical details

| TECHNICAL DETAILS | |
|--------------------------|---|
| Dimensions (mm) | 80 x h147 |
| Nominal pressure (P1) | 350 kPa |
| Inlet pressure (KPa) | from 300 to 350 |
| Flow (L/min) | from 0 to 15 |
| Type of gas supply | oxygen |
| Material | polycarbonate, anodized aluminium and brass |

3.5 Reference standards

| Reference | Title of document |
|--------------------------------------|---|
| MDD 93/42/CEE | European Directive about Medical Devices |
| MDD 2007/47/CEE | Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market |
| Legislative Decree 24/02/1997, n. 46 | Application of the 93/42/CEE Directive about Medical Devices |
| Legislative Decree 25/01/2010, n. 35 | Modifications and additions to the 20/02/97 Decree n. 46 |
| UNI EN ISO 9001 | Managing systems for quality: requirements |
| UNI EN ISO 9000 | Managing systems for quality: basis and vocabulary |
| UNI EN ISO 13485 | Medical Devices - Managing systems for quality - Requirements for regulamentation requirements |
| UNI EN ISO 14971 | Application of risks managing to medical devices |
| UNI CEI EN 980 | Graphic symbols used for medical devices labelling |
| UNI CEI EN 1041 | Information supplied by the medical devices manufacturer |
| CEI EN 62366 | Medical Devices - Application of the utilisation caracteristics 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 |
| UNI EN 15002 | Devices for the measurement of the flow for the connection to terminal units of medical gases distribution systems |
| BS OHSAS 18001 | Managing systems for safety and health at workplace |

3.6 Environmental conditions

Functioning temperature: from 0 to +40 °C

Storage temperature: from 0 to +40 °C

Relative humidity: from 0 to 85 %

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:

- Integrity of the device
- General functionality of the device, as described in the paragraph "Precautionary maintenance"
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- No cuts, holes, tears
- State of use
- Integrity of components

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



Alternative solutions for installation that are not considered in this manual may reduce the security level of the device.

4.3 Installation

The flowmeter should be connected to the suitable distribution of oxygen.

4.4 Functioning

The flowmeter allows the regulation, through a stopcock with a needle valve, of the flow of gas. When the gas passes through the measuring tube, a float rises to the point of balance and dynamic range can be viewed on the scale for the central element indicator.

4.5 Troubleshooting

| PROBLEM | CAUSE | REMEDY | RESIDUAL RISK |
|--------------------------|-------------------------------------|--|---------------|
| Leaks | The O rings are damaged or worn out | Put the device out of service and contact the manufacturer for replacement | None |
| Poor performance | Product life time, worn out | Service at an authorised center and if necessary device substitution | None |
| Strange noise | Possible damage to components | Put the device out of service and contact the manufacturer for replacement | None |
| Unstable outlet pressure | Obstructions, components worn out | Put the device out of service and contact the manufacturer for replacement | None |

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Failure to carry out cleaning operations may involve the risk of cross infection due to the presence of secretions and/or residuals.



Cleaning and disinfection procedures must be carried out by trained staff.

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

Correct **OUTSIDE** cleaning of the device after use or at programmed intervals based on the actual use of the device, require cleaning with a soft cotton cloth dampened with water.

No solvents or abrasive products must be used as they would damage the surface of the device. Do not use inflammable products or soak the device in disinfectant liquid.

The use of water under high pressure is prohibited.

Allow to dry thoroughly before storing. Drying after washing or after use in wet environments must be natural or with a cotton cloth and not forced.

In case of use of disinfectants to verify that they are compatible with the materials specified in the technical.

Do not rinse under water.



5.2 Maintenance

Establish a maintenance program and periodic testing, identifying an reference employee. The person who carries out the maintenance of the appliance has to guarantee the basic requirements indicated by the Manufacturer in the following paragraphs.

All maintenance activities, both precautionary and special, must be registered on documents including technical reports about operations. This register has to be kept for a period of at least 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.

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.

5.2.1 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.



Any maintenance should be done with the devices removed from the cylinders of medical gas supply.

We suggest to:

- clean the surfaces regularly and thoroughly in accordance with the procedures indicated in the paragraph "Cleaning";
- replace any worn or damaged original parts, following the manufacturer's instructions;
- perform periodic inspections (every 3 months or at intervals established by the user) as described below.



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.

The checks to be carried out before and after each use, and at least every three months, are:

- Integrity of the device and its components
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- General functionality of the device, as described below

5.2.1.1 Checks every three months

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.

Checking for leaks from the tap of the flowmeter

- Close – turning clockwise, the flow adjustment tap using the knob of the flowmeter.
 - Connect the outlet connections of the gas to a tubing connector.
 - Put the free end of tube in a vase containing water.
 - Open a source of compressed medical air at a pressure of 3.5 bar using for example a pressure reducer with the correct adjustment for the outlet pressure.
 - Count the number of bubbles generated inside the vase in a period of 10 minutes: if less than 3 bubbles form any leakage is within the acceptable limit. If the leakage is higher, the adjustment needle needs to be substituted by the Manufacturer or by an authorised centre.
- On conclusion of the test the device must be disconnected from the source and from the tubing connector with gas outlet tube.

Checking external leakage

The test described in the following paragraph does not quantify the external leakage and is only a method to check evident leakage of gas

- Tap the gas outlet using a M8 threaded tap.
- Close the adjusting tap using the knob on the flowmeter (turn anti clockwise).
- Open the gas supply to the flowmeter at a pressure of 3.5 bar using medical compressed air using a conform pressure reducer on the outlet.
- Slowly open the adjusting tap using the knob of the flowmeter (turn anti clockwise).
- Using a device to detect gas leakages test to see if any are detected.

When testing has terminated, remove the tap from the gas outlet, disconnect the device from the source and accurately clean the surface as described in the chapter 5.1 "Cleaning".

If any leakage has been detected, contact specialised staff who will put the device through an accurate servicing programme.

5.2.2 Periodical checks

Planned interventions are not required for periodic review by the manufacturer or authorized centre but we recommend to perform cleaning and the controls set out in the paragraphs "Cleaning" and "Maintenance".

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 2 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. Guarantee will be considered void according to lacking conformity to 93/42/CEE Directive about Medical Devices.

6. ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

| CODE | DESCRIPTION |
|-------------|--------------------|
| FL08302B | FL-X Humidifier |

6.2 SPARE PARTS

There aren't any spare parts available 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) | |
| 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/Auth orized centre/ Manufacturer) |
|-------------------------|---|--|---------------|--|
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Warning

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.

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