User's Manual

OXX 200
Compressor/reservoir unit

CE This appliance conforms with the Directive 2004/108/CE

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

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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 and maintenance manual

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

1.3 Symbols used

Symbol	Meaning
	General or specific warnings
	See instructions for use
LOT	Lot number
REF	Product code
CE	The product is compliant with the specifications of the Directive 2004/108/CEE

1.4 Servicing request

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, please contact the Spencer Customer Care Service tel. 0039 0521 541111, fax 0039 0521 541222, e-mail service@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 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). 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 to the device received, inform the manufacturer immediately and avoid use of the device.
- In case of any doubts about 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 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 2004/108/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 user 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's 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.

- The distributor or final user is 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 Spencer Italia S.r.l. expressly disclaims 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.
- All maintenance and periodic check activities must be registered and collected together with their intervention reports (see Maintenance Register) these documents have 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 components/spare parts and/or accessories 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 2004/108/CEE.
- It is necessary at least the assistance of one operator when the device is in use.
- During use, position the device on an horizontal surface, avoiding contact with dust or liquids, and adapt to avoid the overwarming of the device.
- The length of the feeding cable to be directly connected to the source, which is supplied with the compressor/reservoir unit, is 2 m (Ø 2,5 mmq). For longer feeding cables it is necessary to use adequate sections (this should be evaluated by professional users only), otherwise the motor could not function.
- The compressor/reservoir unit has a limited duration service (S2) 30/5, for this reason after 30 minutes of functioning with continuous power supply, a 5 minutes pause is necessary, this will be enough to restablish the conditions of cool functioning; otherwise the motor could burn.
- During the pause period, the device should be disconnected from power supply.

2.1 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 compressor/reservoir unit is ready to be installed on rescue vehicles with a 12 Vdc supply. In a small space the following components are connected: an electric compressor, a non-rebreathing valve, an electrovalve compensating the pressure, a pressure controller with on/off switch and whatever can guarantee a constant delivery of air. Easy to install, it is supplied with feeding cables and connection pipe for air. The device has been made to produce compressed air, not medical air.
The compressed air produced can be used only for the functioning of aspiration systems, such as venturi aspirators.

3.2 Main components

1. Electrical compressor
2. 0n/off switch
3. Pressure relief pilot
4. Threaded exit connection
5. Electric valve in brass
6. Reservoir 4 L in stainless steel
7. Electric cable
8. Cable for motor-reservoir connection
9. Pressure relief tap

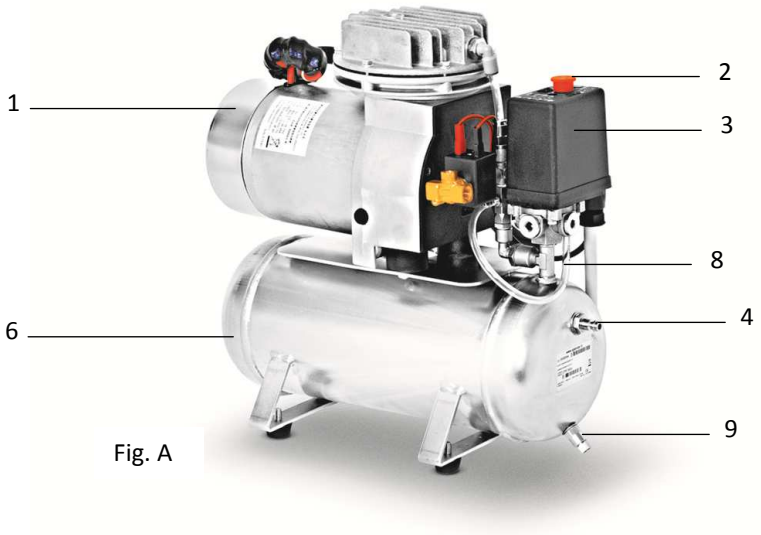

Fig. A

3.3 Models

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

OX02200A OXX 200 Compressor/reservoir unit

3.4 Technical data

Dimensions: 315 x 190 x h340 mm
Weight: 9,5 kg
Power supply: 12 Vcc – 16 A
Absorbtion: 192 W
Capacity: 70 L/min – Rpm 2800 – Serv. 30 min
Maximum pressure: 3,5 bar
Reservoir capacity: 4 L
Isolation class: B
Grade of protection: IP20
Pressure controller: 380 Vmax/60Hz, 15 Amax, 6 bar
Limited duration service: S2 30/5

3.5 Environmental conditions

Functioning temperature: from 0 to 45 °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. 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)
- Correct fixation of all nuts, bolts and screws

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.

In the case that the device appears to be damaged or faulty it must immediately be withdrawn from service until it is repaired or replaced. Do not alter the device for any reason because this could cause damage to the patient or rescuers.

4.3 Functioning

Place the device a horizontal level, well sheltered from dust and spilt liquids, used to avoid an overheating ov the device. The device can be installed on the floor using the four M5 threaded holes and after having removed the four rubber feet. Before connecting the device to the 12 Vdc source with the appropriate cable, make sure the on/off switch on the top side is in the off position.

The length of the feeding cable to be directly connected to the source, which is supplied with the compressor/reservoir unit, is 2 m (Ø 2,5 mmq). For longer feeding cables it is necessary to use adequate sections (this should be evaluated by professional users only), otherwise the motor could not function.

Connect the red cable to the positive pole of the 12 Vdc source and the black cable to the negative pole. Make sure the pressure relief tap situated at the base is completely closed, then lift the switch to the on position. As a result the electric compressor will start to work and it will supply air to the reservoir.
When the internal pressure of the reservoir reaches the value of 3,5 bar the pressure switch will automatically interrupt the supply. It is now possible to use the air stored inside the reservoir through the rapid exit connection or possibly by connecting this exit with other devices (e.g. air outlets, lung ventilators).
If the on/off switch is on the on position during the use of the device, when the air pressure inside the reservoir drops to 2,4 bar, the pressure switch will automatically activate the electric compressor which will bring the pressure value back to 3,5 bar. However it is possible, in any moment, to interrupt the functioning of the electric compressor by moving the switch to the off position.
After some use of the electric compressor, condensation produced inside the reservoir must be released by unscrewing the pressure relief knob placed at the bottom of the reservoir. The pressure relief tap can be closed when all the water has been expelled out of the reservoir.

The compressor/reservoir unit OXX 200 has a limited duration service (S2) 30/5, for this reason after 30 minutes of functioning with continuous power supply, a 5 minutes pause is necessary, this will be enough to restablish the conditions of cool functioning; otherwise the motor could burn. During the pause period, the device should be disconnected from power supply.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The compressor does not work	Wrong cable connection between the compressor and the feeder	Check out the correct connection of the positive pole with the negative one
Presence of water with the air supplied by the compressor	Production of condensation inside the reservoir	With a pair of pliers use the pressure relief valve (n.9 fig. A) in order to expel the water present
The reservoir fails to fill	Incorrect connection of the quick coupling	Check the correct position of the coupling
	Quick coupling is broken	Substitute the damaged piece

5. MAINTENANCEAND 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.

Remove all possible traces of dust with a clean piece of cloth and making sure you that the original qualities of the compressor are not modified. Do not wash the device and never use solvents or stain removers. In case of desinfection, only use products that do not have solvent or aggressive components on the materials of the device. We suggest to use the detergent Spencer STX 98 (code ST50010C).

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 2004/108/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

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

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)
- Correct fixation of all nuts, bolts and screws

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 2004/108/CEE.

The person responsible for routine maintenance must identify damaged/worn parts, but the replacement or restoration of them can only be carried out by the manufacturer or or by an authorized service centre.
For other replacement/repair activities contact the Manufacturer or an authorized centre.

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 2004/108/EEC.

5.2.2 Periodic maintenance

The device must be serviced by the manufacturer or by an authorised centre, every year.

If the correct revision is not carried out, the CE branding will no longer be considered valid as the product will no longer be compliant with the 2004/108/CEE Directive for Medical Devices and consequently it is no longer compliant with the safety standards declared by the Manufacturer at time of 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.

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 both the guarantee and the conformity to the Medical Devices Directive 2004/108/CEE.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

There aren't any accessories for this device.

6.2 Spare parts

OX02002A	OXX 400 Air compressor
OX02030A	OXX 300 Reservoir in stainless steel

ATTACHMENT A – TRAINING REGISTER

The product must be used only by trained personnel who have attended specific training for the use of this device and just for products with similar characteristics.

Keep this document at least 10 years after the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc.)	Trainer
	Basic training	Advanced training		

ATTACHMENT B – MAINTENANCE REGISTER

Keep this document at least 10 years from the end of life of the device.

Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

Code and description of the device	
Purchase date	
Lot (LOT) or serial number (SN)	
Bought by	

SERVICE DATE	KIND OF SERVICE (Maintenance/ check/ extension of life span)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (Operator/ Authorized centre/ Manufacturer)