User's Manual

Oxymask
Masks for oxygen therapy

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

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First edition: 22/05/06
Rev.3: 07/07/17

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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 0123	The product is compliant with the specifications of the Directive 93/42/CEE
	Contains phthalates DEHP
LATEX FREE	Latex free
	Single use device

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. – 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

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, the CE mark and 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.
- Never leave the patient without the assistance of at least one operator when using the medical device.
- 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 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

- The masks for oxygen therapy may be used only by operators trained in their use. The operator must be able to: explain to the patient the oxygen therapy procedures, help the patient to assume the most appropriate position for the therapy, connect any additional devices to the mask, use properly and safely all devices and oxygen distribution systems, check the proper functioning of all equipment, know how to interpret all the physiological responses of the patient, know how to evaluate the effectiveness of therapy.
- The mask should not be exposed or come into contact with thermal ignition sources and flammable agents.
- The administration of oxygen in the presence of hydrocarbons generates explosive mixtures.

- Do not use the mask in polluted environment.
- Check the condition of the product when opening its box and before each use.
- These devices are disposable
- Oxymask contain phthalates DEHP type.

2.3 Contraindications and side effects

The use of this device, if applied by operators trained to oxygen therapy techniques, does not present any contraindications or collateral effects directly connected with the use of Oxymask. The practice of oxygen therapy has side effects that must be carefully evaluated by the operator taking into consideration the patient's condition and the expected duration of the therapy.

The presence of phthalates DEHP may have kind of events related to the toxicity of this substance.

The device, however, has successfully passed the test of in vitro cytotoxicity, irritation and sensitization of the skin to which it was subjected in an accredited laboratory.

3. PRODUCT DESCRIPTION

3.1 Intended use

Oxymask are an optimal solution for oxygen therapy applications. The masks are available in various models, according to the the concentration of oxygen the patient should be treated with. Intervention of the patient on the device is not to be expected.

3.2 Main components

1. Adjustable strap
2. Flexible metal clip for nose fixation
3. Mask body
4. Oxygen tube inlet
5. O_2 anti-crushing tube (where present)
6. Venturi connections
7. Corrugated tube (only Venturi masks)

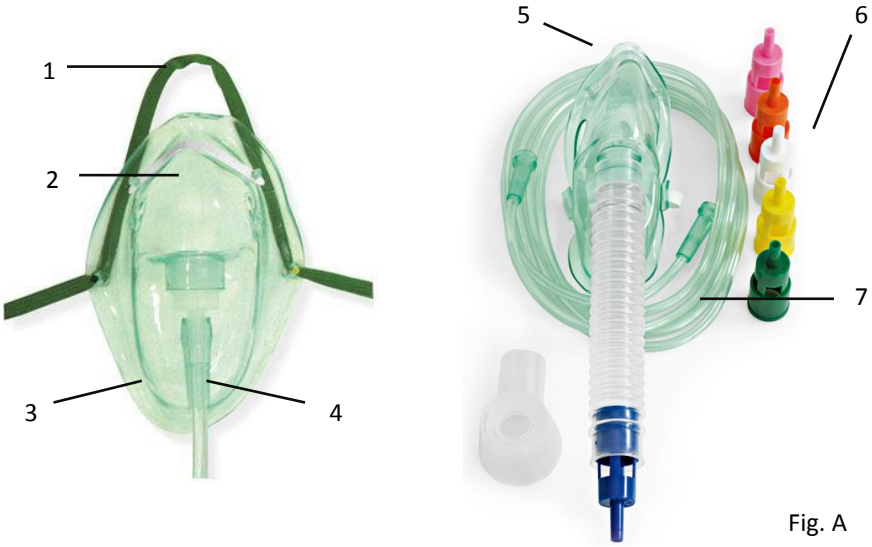

Fig. A

In high concentration models the **reservoir bag** is present (not shown).

3.3 Models

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

OX20133A	OXYMASK 50 Medium concentration mask, paediatric, 10 pcs
OX20139A	OXYMASK 50 Medium concentration mask, adult, 10 pcs
OX20136A	OXYMASK 100 Variable concentration mask, paediatric, 10 pcs
OX20132A	OXYMASK 100 Variable concentration mask, adult, 10 pcs
OX20137A	OXYMASK 150 High concentration mask, paediatric, 10 pcs
OX20134A	OXYMASK 150 High concentration mask, adult, 10 pcs

3.4 Technical data

Model	Length of corrugated tube (cm)	Length of anti-crushing tube (m)	Latex Free
Oxymask 50	/	2	Yes
Oxymask 100	15	2	Yes
Oxymask 150	/	2	Yes

Component	Material
Mask body	PVC
Oxygen tube inlet/Venturi connections	PP
Anti-crushing tube and corrugated tube	PVC
Reservoir bag (where present)	PVC

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 ISO 15223-1	Medical devices - Symbols for use in the medical device labels, labelling and information to be provided. Part 1: general requirements
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
UNI EN ISO 10993-1	Biological Evaluation of Medical Devices'—Part 1: Evaluation and Testing

3.6 Environmental conditions

Functioning temperature: from -10 to +40 °C
Storage temperature: from -15 to +60 °C
Store the masks in a closed environment, in conditions which ensure integrity and protection from dust and atmospheric agents. Do not store them under other objects and/or materials that might compromise their integrity.

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 and cool area, free from humidity

4.2. Preparation

When receiving the mask, it should be checked visually, and before every use, to ensure the integrity and clearing of the device.

4.3. Functioning

1. Make sure the oxygen tube is fixed correctly to the oxygen source.
2. Fix one side of the oxygen tube to the inlet of the mask.
3. Regulate the oxygen delivery as prescribed by the medical personnel.
4. Apply the mask on the face of the patient, covering both nose and mouth.
5. Pass the elastic strap behind the head and the ears of the patient.
6. Regulate the tension of the elastic strap, pulling both ends of the strap through the dedicated parts of the mask.
7. Adapt the flexible metal part of the mask to the shape of the patient's nose

For Venturi masks, the suggested parameters are the following:

O_2 supplied percentage	Colour	Suggested O2 flow
24 %	Blue	4 l/min
28 %	White	4 l/min
31 %	Orange	6 l/min
35 %	Yellow	8 l/min
40 %	Red	8 l/min
50 %	Pink	10 l/min
60 %	Green	15 l/min

4.4. Troubleshooting

PROBLEM	CAUSE	REMEDY
The mask shows structural/functional damage	Lesion of one or more components	Immediately place the device out of service and replace it with a similar one. Report the problem to the manufacturer.
Detachment of the tube from the mask	Device not properly stored, placed under heavy materials or high temperature	Immediately place the device out of service and replace it with a similar one
Break of the elastic strap	Device not properly stored or has been exercised excessive tension on the elastic	Immediately place the device out of service and replace it with a similar one
Metal clip missing	The clip is accidentally detached	Immediately place the device out of service and replace it with a similar one. The device must be kept with the original packaging.

5. MAINTENANCE AND CLEANING

Oxymask are **disposable devices**, therefore they do not require programmed operations of maintenance and cleaning.
Checks to be carried out before each use are as follows:

- Cleanliness of the device
- Absence of cuts, holes, tears on the structure
- State of integrity and presence of any damages to the device due to possible unsuitable storage conditions.
- Expiration date or average life span, if any.

In order to prevent possible damage to the packaging that may affect the state of cleanliness and integrity of the device, it is necessary to ensure compliance with the conditions set out in paragraph 4.1.

The device, when stored as described in the following instructions, needs to be retired to the overcoming of the 5th year of life (or at least manifestation of loss of integrity of materials).
Spencer Italy S.r.l. declines any responsibility for the incorrect operation or damage caused by reuse of single-use devices or arising from their employment over the period of their expected life span.

6. ACCESSORIES AND SPARE PARTS

There are no accessories or replacement parts for these products.

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.