User's Manual

Spencer Mask
Resuscitation face masks

CE 0123 This appliance conforms with the Directive 93/42/CEE "Medical Devices"

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

INDEX

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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

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

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, 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 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 resuscitation masks must only be used by personnel trained in cardio-pulmonary resuscitation techniques (CPR or ACLS).
- The mask should not be exposed to combustion heat sources and inflammable agents.
- The use of oxygen in the presence of hydrocarbons creates explosive mixes.
- Do not use the mask in a polluted environment.
- When opening its box and before every use, check the general condition of the device.
- Spencer Mask resuscitation masks should be sterilized after each use. Their re-use without proper cleaning can cause cross-infections. Do not use the device over the life time established in this manual.

2.3 Contraindications and side effects

The use of the device, if used by personnel, trained in cardio-pulmonary resuscitation techniques (CPR or ACLS), does not present any contraindications and side effects.

3. PRODUCT DESCRIPTION

3.1 Intended use

The resuscitation masks are used for assisted and controlled ventilation; they can be used with both manual resuscitators and active medical devices. The structure is modelled anatomically and ergonomically to ensure a perfect seal on the face of the patient and an optimal grip for the operator. The device is intended for use in first aid procedures and for not more than 24 hours.

3.2 Main components

1 Cushion
2 Shell
3 Valve for inflating the cushion
4 Connection to patient valve

Fig. A

3.3 Models

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

RM20700A	Spencer Mask size 0 polycarbonate
RM20702A	Spencer Mask size 2 polycarbonate
RM20704A	Spencer Mask size 4 polycarbonate
RM20705A	Spencer Mask size 5 polycarbonate
RM20710B	Spencer Mask 4 sizes polycarbonate
RM20800A	Spencer Mask size 0 polysulphonate
RM20802A	Spencer Mask size 2 polysulphonate
RM20804A	Spencer Mask size 4 polysulphonate
RM20805A	Spencer Mask size 5 polysulphonate
RM20810B	Spencer Mask 4 sizes polysulphonate

3.4 Technical data

Component	Material
Shell	Polycarbonate or polysulphonate depending on models
Cushion	Silicone rubber
Cushion cap	Removable PP
Connection	Silicone rubber

The cap on the valve of the cushion must be removed before performing the sterilization cycles.

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 10651-4 § 4.3	Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators
UNI EN ISO 10993-1	Biological evaluation of medical devices. Evaluation and testing
UNI EN ISO 10993-12	Biological evaluation of medical devices Part 12: Sample preparation and reference materials
UNI EN ISO 10993-5	Tests for in vitro cytotoxicity
Italian Pharmacopoeia Edition and European Pharmacopoeia current edition	

3.6 Environmental conditions

Functioning temperature: from -18 to +50 °C
Storage temperature: from -20 to +70 °C

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 area, free from humidity.

4.2. Preparation

On receipt of the product, the mask requires visual inspection, which must be repeated before each use to verify its integrity. The mask is used with the ventilation equipment available.

4.3. Functioning

1. Position the patient in laying horizontal position, keeping his face pointed upwards.
2. Free the patient's mouth and throat from any obstacles or body liquids.
3. It is advisable to introduce an oropharyngeal airway into the patient's mouth before using a manual resuscitator.
4. Stand behind the patient's head, move his head backwards, then holding it close at the same time pull his chin upwards and backwards.
5. Put the mask on the patient's face, fitting both mouth and nose and keeping it firm with your forefinger and thumb.
6. Check the patient's face and the colour of his lips.
7. Make sure to use a mask which covers perfectly both mouth and nose (including nasal pyramid and lowerlip), excluding however the chin, which should remain uncovered.
8. Free the airways by removing, if necessary, vomiting, liquids, or objects that create obstruction.
9. Hyperextend the patient's neck with due caution.

4.3.1. Disassembling the mask

Disassemble the transparent part of the mask from the cushion. Perform the operation very carefully in order to avoid damaging one or more components of the mask. Before starting the sterilization procedure in autoclave, make sure to remove the cap on mask. When finished the cleaning operations, verify the integrity of all components and proceed with the reassembly of the mask.

4.4. Troubleshooting

PROBLEM	CAUSE	REMEDY
The mask looses air, although fixed correctly	The patient has a moustache or a beard the face is sweaty	In case of beard or moustache, try to push the mask a bit stronger on the patient's face. In case of sweaty faces dry the face with a towel
	The size of the chosen mask is not compatible with the face of the patient	Replace the mask with one that is compatible with the dimensions and structure of the patient's face
The mask shows structural/functional damage	One or more components are worn out	Put immediately the device out of service and contact the service centre
The silicone cushion is torn	Misuse or exceeding the number of sterilization cycles guaranteed	Replace the mask

5. MAINTENANCE AND CLEANING

5.1. Cleaning

Not cleaning or sterilizing the device may cause cross-contaminations due to the presence of body fluids or residuals. Before starting the cleaning procedure, make sure to have disassembled the mask and all its components.

Washing

For correct washing a detergent should be used. Use lukewarm water for all washing operations. Avoid the use of aggressive detergents or those containing phenol. Make sure to wash away any trace of detergent and to dry every component of the mask carefully. Detergent residuals may have negative effects on the integrity and durability of the mask.

Disinfection

For correct disinfection use ethylene oxide according to the validated cycle parameters, reported in the UNI EN ISO 11135-1 norm) or sterilizing. It is necessary to determine the method of disinfection to apply to the masks.

Sterilization

Autoclave (according to the validated cycle parameters, reported in the UNI EN ISO 17665-1 norm. To make a proper sterilization it is mandatory that the mask is disassembled in all its parts.
Make sure to remove the cushion cap, which is not compatible with sterilization in autoclave. The cap can be cleaned with detergent or separately sterilized using ethylene oxide.
The use of the autoclave for sterilization decreases the lifetime of the mask.
The Spencer Masks are guaranteed for a maximum of 40 cycles of sterilization.

The cleaning methods are summarized in the chart below:

Cleaning methods	Spencer Mask polycarbonate	Spencer Mask polysulphonate
Washing with detergent (avoid detergents containing phenol)	Yes	Yes
Disinfection with disinfectant	Yes	Yes
Sterilization with ethylene oxide through a validated cycle (UNI EN ISO 11135-1)	Yes	Yes
Sterilization with autoclave through a validated cycle (UNI EN ISO 17665-1)	121 °C	134 °C

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.

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:

- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure
- State of wear and damage to the device due to the number of sterilization cycles undergone.
- Expiration date or average life-time, if any.

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.

5.2.2 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, when used as described in the following instructions, needs to be retired to the overcoming of the 3rd year of life starting from the purchase date or when exceeding the number of sterilization cycles described in this manual.

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 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 93/42/CEE.

6. ACCESSORIES AND SPARE PARTS

There are nor accessories or replacement parts for these products.