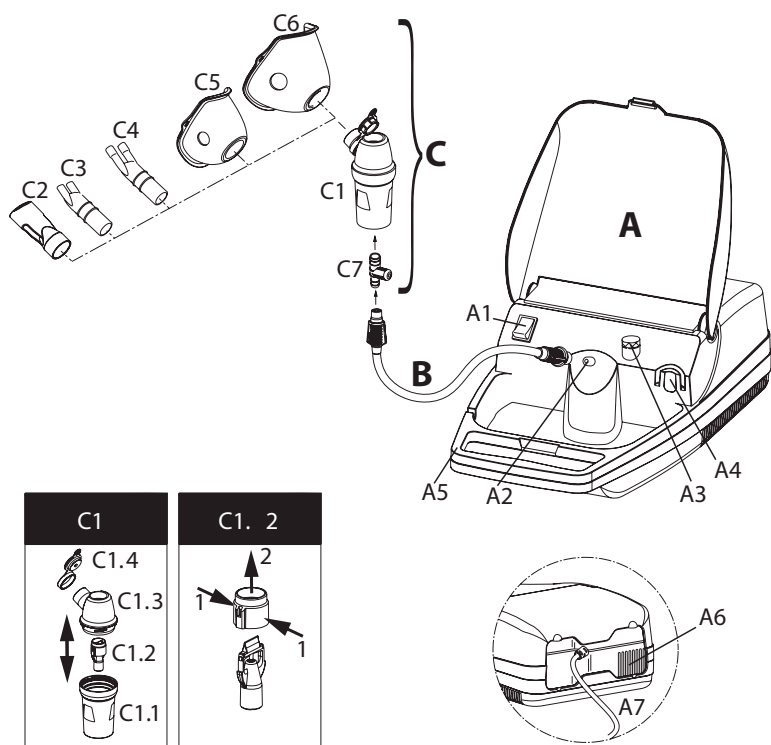


# Liberty

## Health Products

### INSTRUCTIONS FOR USE MANUAL



Assembly diagram



## AEROSOL THERAPY UNIT

Congratulations on your purchase and thank you for choosing our unit. Our goal is to fully satisfy consumers by offering them cutting-edge systems for the treatment of respiratory tract ailments. Carefully read these instructions and keep them in a safe place for future reference. **Use the unit only as described in this instruction manual. This is a medical device for home use designed to administer nebulizer medications prescribed or recommended by your physician.**

### THE STANDARD COMPONENTS AND ACCESSORIES OF THE UNIT INCLUDE:

- |                                            |                                       |
|--------------------------------------------|---------------------------------------|
| <b>A - Aerosoltherapy unit (main unit)</b> | <b>C - Accessories</b>                |
| A1 - On/off switch                         | C1 - RF6 Basic <sup>2</sup> nebuliser |
| A2 - Air outlet port                       | C1.1 - Lower part                     |
| A3 - Air filter                            | C1.2 - Complete nozzle                |
| A4 - Nebuliser holder                      | C1.3 - Upper part                     |
| A5 - Carrying handle                       | C1.4 - Top ventilation cap            |
| A6 - Cable compartment                     | C2 - Mouthpiece                       |
| A7 - Power cord                            | C3 - Child nasal prong                |
| <b>B - Connection tube</b>                 | C4 - Adult nasal prong                |
| <b>(main unit / nebuliser)</b>             | C5 - Child mask                       |
|                                            | C6 - Adult mask                       |
|                                            | C7 - Manual nebulization control      |

### IMPORTANT SAFEGUARDS

- This M.D. is also intended for direct use by the patient.
- Before using the device for the first time and periodically during the product's life, check the integrity of its structure and of the power cable, making sure that there is no damage; if it is damaged, do not insert the plug and take the product immediately to an authorized technical assistance centre or to your local dealer.
- Should your device fail to provide the expected performance, contact the authorised service centre for clarifications.
- The average life span of accessories is 1 year; however, we recommend you replace the nebulizer every 6 months in intensive use (or earlier, if the nebulizer is blocked) to always ensure maximum therapeutic effect.
- Children and disabled persons should always use the unit under strict supervision of an adult who has read this manual.
- Several parts of the device are small enough to be swallowed by children; therefore keep the device out of reach of children.
- Do not use the tubes and the cords of the device for purposes other than those specified as they may cause strangulation hazard; utmost attention must be paid to children and persons with special needs; usually, such persons are not capable of assessing the hazard correctly.
- The unit should not be used in the presence of anaesthetic mixture inflammable with air, oxygen or nitrous oxide.
- Keep the cord away from heated surfaces.
- Keep the power supply cord away from animals (for example rodents) as they may damage the insulation of the power supply cord.
- Do not handle the unit with wet hands. Do not use the device in humid environments (e.g. while taking a bath or shower). Do not immerse the device

in water; should this accidentally occur, unplug the device immediately. Do not remove or touch the device immersed in water before pulling out the plug. Take the device immediately to an authorized service center or to your local dealer.

- Only use the device in dust-free environments; otherwise, therapy may be compromised.
- The casing of this unit is not protected against the penetration of liquids. Do not wash the device under running water or submerge in water. Keep away from splashing water or other liquids.
- Do not expose the device to high temperatures.
- Do not put the device near heat sources, direct sunlight, or in hot environments.
- Do not obstruct or insert any objects in the filter or in its housing.
- Do not obstruct the air vents placed on both sides of the unit.
- During use, always place the unit on a firm surface clear of obstacles.
- Check that there is no material obstructing the air vents before each use.
- Do not place any objects inside the air vents.
- The average operational life of the compressor is 400 hours.
- Repairs must be performed by authorized personnel only. Any unauthorized repairs will void the warranty and may pose a safety hazard for the user.  
WARNING: Do not modify this equipment without authorization of the manufacturer
- The Manufacturer, the Retailer and the Importer are responsible for the safety, reliability and performance of the device only if: a) the device is used in accordance with the operating instructions b) the electrical system of the premises where the device is used is in compliance with current laws.
- Interactions: The materials used that come into contact with medications have been tested with a wide range of medications. However, due to the variety and continuous evolution of medication, the possibility of a chemical interaction cannot be excluded. We recommend that once the medication has been opened you should use it as soon as possible and avoid prolonged contact of the medication with the nebulizer.
- The manufacturer should be contacted for reporting problems and/or unexpected events related to device operation.
- The amount of time required between preservation conditions and use is approximately 2 hours.

## INSTRUCTIONS FOR USE

**Before each use, clean hands thoroughly and clean the device as described in the section on “CLEANING SANITISATION DISINFECTION”. During use, it is advisable to protect yourself from any dripping. It is recommended that each person use their own nebulizer cup and accessories to prevent risk of infection due to contamination. This device is suitable for the administration of medical substances and not, for which the administration via aerosol is foreseen; these substances are to be in any case prescribed by the Doctor. In case of too thick substances, the dilution with a suitable physiological solution could be needed, according to the medical prescription.**

1. Plug the power cord (A7) into a power socket corresponding to the voltage of the unit. This must be positioned so that it is not difficult to make the disconnection from the mains.
2. Assemble the nozzle as indicated in the “Connection diagram” in point C1.2. Insert the complete nozzle in the bottom part (C1.1). Insert the Upper ventilation cover (C1.4) in the upper part (C1.3) as shown in the “Connection diagram” in point C1.
3. Pour the medication prescribed by the physician into the lower part (C1.1).

Close the nebuliser by turning the upper part (C1.3) clockwise.

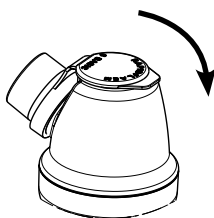
4. Connect accessories as indicated in the "Connection diagram" on the cover.
5. Sit comfortably holding the nebuliser in your hand, place the mouthpiece onto your mouth or alternatively use the nose piece or mask. Should you opt for the mask accessory, place it on your face as shown in the picture (with or without using the elasticated strap).



The cap (C1.4) provided with the nebuliser RF6 Basic<sup>2</sup> makes it possible to deliver the medication in 2 modes:

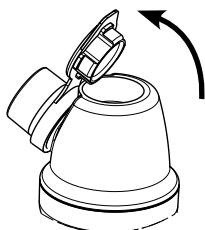
**"standard mode",**

for optimum delivery and minimum waste of medication



**"high speed mode"**

for a quicker treatment

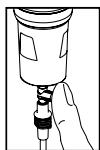


6. Start the unit by means of switch (A1) and Inhale gently and deeply; after inspiration we recommend to hold your breath for a moment in order to allow inhaled aerosol droplets to deposit. Then, exhale slowly.
7. When the treatment is finished, turn off and unplug the unit.

**WARNING:** If after the therapy session moisture accumulates in the tube (B), remove the tube from the nebulizer and dry it using the compressor air flow; this operation will prevent mold from forming inside the tube.

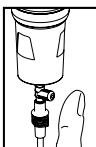
**USE OF NEBULIZATION MANUAL CONTROL**

To achieve continuous nebulisation action you should not use the manual nebulisation control (C7), especially in the case of children or persons with reduced physical, sensory, or mental capabilities. The manual nebulisation control is useful for limiting dispersion of the medication in the surrounding environment.



To start nebulizing close with a finger the hole of the nebulizer manual control (C7) and breathe in gently; we recommend to hold your breath for a moment so that the inhaled aerosol droplets can be

deposited,



meanwhile, to disable nebulizing, remove your finger from the hole of the nebulizer manual control to avoid the waste of drug, optimizing its acquisition. Then

exhale slowly.

## CLEANING SANITISATION DISINFECTION

*Switch off the device before any cleaning procedure and unplug the power cable from the socket.*

### DEVICE AND TUBING EXTERIOR

Use only a damp cloth with antibacterial soap (non-abrasive and with no solvents of any sort).

### ACCESSORIES

Open the nebuliser by turning the upper part (C1.3) anticlockwise, remove the nozzle (C1.2) from the upper part (C1.3). Disassembly the complete nozzle by pressing as shown by the 2 arrows in the "Connection diagram" in point C1.2.

Then proceed according to the following instructions.

### SANITISATION

Before and after each use, sanitise the nebuliser cup and the accessories, choosing one of the methods described below.

**method A:** Sanitise accessories **C1.1-C1.2-C1.3-C1.4-C2-C3-C4-C5-C6-C7** under potable hot water (approximately 40 °C) with a gentle, non abrasive dish detergent.

**method B:** Sanitise accessories **C1.1-C1.2-C1.3-C1.4-C2-C3-C4-C5-C6-C7** in the dishwasher with a hot cycle.

**method C:** Sanitise accessories **C1.1-C1.2-C1.3-C1.4-C2-C3-C4-C5-C6-C7** by immersing them in a solution of 50% water and 50% white vinegar, then rinse thoroughly under potable hot water (approximately 40 °C).

If you want to also perform the cleaning for DISINFECTION, jump to the DISINFECTION paragraph.

After having sanitised the accessories, shake them vigorously and place them on a paper towel. Alternatively, dry them with a jet of hot air (for example, a hair dryer).

### DISINFECTION

After sanitising the nebuliser cup and the accessories, disinfect them choosing one of the methods described below.

**method A:** Accessories **C1.1-C1.2-C1.3-C1.4-C2-C3-C4-C5-C6-C7** can be disinfected. The disinfectant must be an electrolytic chloroxidizer (active principle: sodium hypochlorite) specific for disinfecting, which is available in any pharmacy.

#### Implementation:

- Fill a container big enough to hold all of the parts to disinfect with a solution of potable water and disinfectant, according to the proportions indicated on the packaging of the disinfectant.
- Completely immerse each part in the solution, taking care to avoid the formation of air bubbles on the parts. Leave the parts immersed for the amount of time indicated on the packaging of the disinfectant associated with the concentration chosen for the solution.
- Remove the disinfected parts and rinse abundantly with warm potable water.
- Dispose of the solution following the instructions provided by the disinfectant manufacturer.

**method B:** Sanitise the accessories **C1.1-C1.2-C1.3-C1.4-C2-C3-C4-C7** by boiling them in water for 10 minutes; use demineralised or distilled water to prevent calcium deposits.

**method C:** Sanitise the accessories **C1.1-C1.2-C1.3-C1.4-C2-C3-C4** with a hot steam steriliser for baby-bottle (not the microwave type). Perform the process faithfully following the instructions of the steriliser. To ensure that the disinfection is effective, choose a steriliser with an operating cycle of at least 6 minutes.

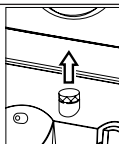
After having disinfected the accessories, shake them vigorously and place them on a paper towel. Alternatively, dry them with a jet of hot air (for example, from a hair dryer).

**At the end of each use store the device complete with accessories in a dry place away from dust.**

## AIR FILTERING

The unit is equipped with an air filter (A3) which should be replaced when dirty or when its colour changes.

Regular replacement of the filter is required to help and ensure correct performance of the compressor. Check the filter on a regular basis. Contact your local dealer or authorized service center for spare filters. To replace the filter take it out by pulling it as shown in figure. The filter is designed to remain fixed in its housing.



**Do not replace the filter during use.**

**Only use original accessories and spare parts by Flaem, we disclaim any liability in the event of using non original spare parts or accessories.**

## SYMBOLS

 CE Medical Marking ref. Dir. 93/42 EEC and subsequent amendments. Complies with EN 60601-1-11.



Class II device



Important: check the operating instructions



"OFF" for part of Equipment



"ON" for part of equipment



Complies with: European standard EN 10993-1 "Biological Evaluation of Medical Devices" and European Directive 93/42/EEC "Medical Devices". Phthalate-free. In compliance with: Reg. (EC) no. 1907/2006



Minimum and maximum ambient temperature



Serial number of device



Manufacturer



Type BF applied part



Alternating current



Enclosure protection rating: IP21. (Protected against solid bodies over 12 mm. Protected against access with a finger; Protected against vertically falling water drops).



Minimum and maximum air pressure



Minimum and maximum humidity

## TROUBLESHOOTING

Switch off the device before any procedure and unplug the power cable from the socket.

| PROBLEM                                                   | CAUSE                                                                 | SOLUTION                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------|-----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The device does not work                                  | The power cable has not been correctly inserted into the power socket | Correctly insert the power cable in sockets.                                                                                                                                                                                                                                          |
| The device does not nebulize or nebulizes insufficiently. | The medication has not been inserted in the nebulizer                 | Pour the right amount of medication in the nebulizer                                                                                                                                                                                                                                  |
|                                                           | The nebulizer has not been properly fitted.                           | Disassemble the nebulizer and reassemble it correctly as shown in the connection diagram on the cover.                                                                                                                                                                                |
|                                                           | The nebulizer nozzle is clogged                                       | Disassemble the nebulizer, remove the nozzle and perform cleaning operations.<br>Failure to remove medication deposits from the nebulizer affects its efficiency and operation. Strictly comply with the instructions contained in the "CLEANING, SANITISATION, DISINFECTION" chapter |
|                                                           | The air pipe is not correctly connected to the device                 | Ensure the device's accessories are properly connected to the air intake (see connection diagram on the cover).                                                                                                                                                                       |
|                                                           | The air pipe is bent, damaged or twisted                              | Unwind the pipe and ensure it is not crushed or punctured. If necessary replace it.                                                                                                                                                                                                   |
|                                                           | The air filter is dirty                                               | Replace the filter                                                                                                                                                                                                                                                                    |
| The apparatus is noisier than usual                       | The Filter is not correctly inserted in its housing                   | Fully and properly insert the Filter in its housing                                                                                                                                                                                                                                   |

If after verifying the above mentioned conditions the device should not operate properly, contact your trusted retailer or the nearest authorized FLAEM service center.

## DISPOSAL OF DEVICE:



In conformity with Directive 2012/19/EC, the symbol shown on the device to be disposed of indicates that it is considered as waste and is therefore subject to "sorted waste collection". The user must therefore take (or have taken) the above waste to a pre-sorted waste collection centre set up by the local authorities, or else give it back to the dealer when purchasing a new appliance of the same type. Pre-sorted waste collection and the subsequent treatment, recovery and disposal operations favor the production of appliances made of recycled materials and limit the negative effects of any incorrect waste management on the environment and public health. The unlawful disposal of the product by the user could result in administrative fines as provided by the laws transposing Directive 2012/19/EC of the European member state or of the country in which the product is disposed of.

## TECHNICAL FEATURES

### Mod. Liberty®

**ARTG No. 92850**

|                        |                   |
|------------------------|-------------------|
| Voltage:               | 230V ~ 50Hz 130VA |
| Max pressure:          | 1.8 ± 0.3 bar     |
| Compressor air output: | 9 l/min approx    |
| Sound level (at 1 m):  | 57 dB (A) approx  |
| Operation:             | Continuous        |

### Operating conditions:

|                       |                       |
|-----------------------|-----------------------|
| Temperature:          | min 10°C; max 40°C    |
| RH Air humidity:      | min 10%; max 95%      |
| Atmospheric pressure: | min 69KPa; max 106KPa |

### Storage conditions:

|                       |                       |
|-----------------------|-----------------------|
| Temperature:          | min -25°C; max 70°C   |
| RH Air humidity:      | min 10%; max 95%      |
| Atmospheric pressure: | min 69KPa; max 106KPa |

|                         |              |
|-------------------------|--------------|
| Dimensions (W)x(D)x(H): | 117x31x10 cm |
| Weight:                 | 2.100 Kg     |

### APPLIED PARTS

|                            |                                          |
|----------------------------|------------------------------------------|
| Type BF applied parts are: | patient accessories (C2, C3, C4, C5, C6) |
|----------------------------|------------------------------------------|

### RF6 Basic<sup>2</sup> nebuliser

|                                 |          |
|---------------------------------|----------|
| Medication minimum capacity:    | 2 ml     |
| Medication maximum capacity:    | 8 ml     |
| Operating pressure (with neb.): | 0.65 bar |

| MMAD (µm) <sup>(2)</sup> |                 | BREATHABLE FRACTION < 5 µm (FPF) <sup>(2)</sup> |                 | DELIVERY ml/min <sup>(1)</sup> (approx) |                 |
|--------------------------|-----------------|-------------------------------------------------|-----------------|-----------------------------------------|-----------------|
| Standard mode            | High speed mode | Standard mode                                   | High speed mode | Standard mode                           | High speed mode |
| 3.8                      | 4.0             | 62%                                             | 63%             | 0.25                                    | 0.32            |

(1) data detected according to Flaem I29-P07.5 internal procedure

(2) In vitro testing certified by TÜV Rheinland LGA Products GmbH - Germany in compliance with the European Standard EN 13544-1 for nebulising systems. Further details are available upon request.

## ELECTROMAGNETIC COMPATIBILITY

This device has been designed to meet the current requirements for electromagnetic compatibility (EN 60 601-1-2). Electromedical devices require special care during installation and use, with respect to EMC requirements it is therefore required that they be installed and/or used according to the manufacturer's specification. Risk of potential electromagnetic interference with other devices. RF mobile or portable radio and telecommunications devices (mobile telephones or wireless connections) can interfere with the functioning of electromedical devices. For additional information contact [info@axishealth.com.au](mailto:info@axishealth.com.au). The appliance may be susceptible to electromagnetic interference in the presence of other devices used for specific diagnoses or treatments. The Manufacturer reserves the right to make technical and functional changes to the product without notice.

## Warranty

Axis Health warrants that the product supplied is free from faults or defects in materials or workmanship for 2 years (24 months) on the main unit only (excluding accessories) from the date of original purchase.

This warranty excludes defects, faults or a failure to perform as intended caused by the product not being used in accordance with instructions, accidental or intentional damage, normal wear and tear, misuse, being altered or tampered with by unauthorised persons or any other reasons allowed by Australian Consumer Law.

The benefits provided to the consumer by this warranty are in addition to other rights and remedies available to the consumer under the law.

This warranty is given by:

AXIS HEALTH  
405-409 Ferntree Gully road  
Mount Waverley VIC 3149  
T\_ (03) 9922 0300  
Email: [info@axishealth.com.au](mailto:info@axishealth.com.au)

To claim this warranty, the consumer must cease using the product immediately and, in the first instance, contact the supplier from whom the item was purchased detailing the problem and arranging the return of the faulty item for inspection (including testing if applicable) or to Axis Health for a remedy under this warranty. Proof of purchase must accompany any claim on this warranty.

If after inspection and/or testing the product is found to be faulty or defective in materials or workmanship, the supplier or Axis Health will at its discretion repair or replace the product. If the item is no longer available, Axis Health reserves the right to replace it with the nearest corresponding item of no lesser value or arrange a refund through the supplier from which the item was originally purchased.

The costs of returning the faulty or defective item to the supplier or Axis Health must be borne by the consumer.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.



DISTRIBUTED BY:

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