5020

# EN Aerosol Therapy Unit

nuvita
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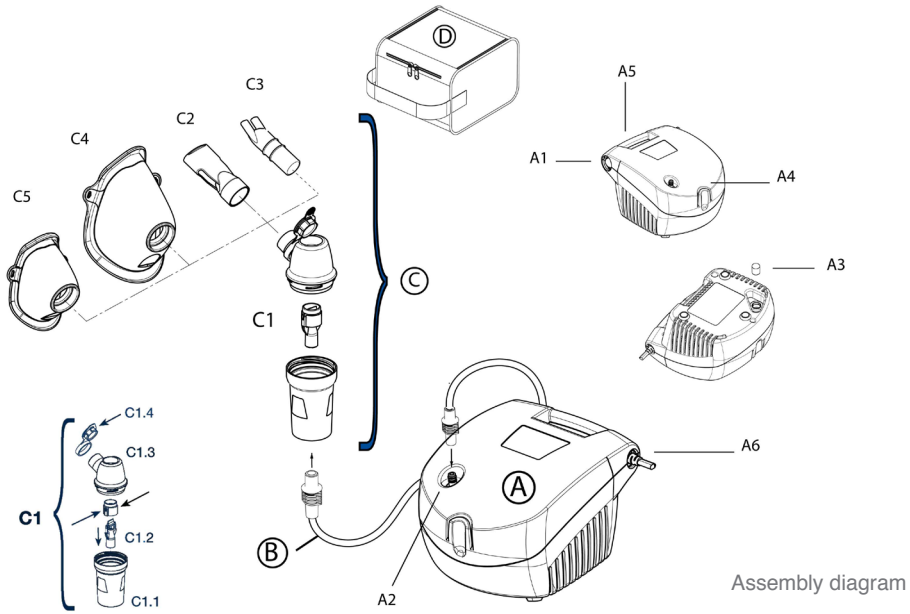
Congratulations on your purchase and thank you for choosing our unit. Our goal is to fully satisfy our customers by offering them cutting-edge systems for the treatment of respiratory tract aliments.
Carefully read these instructions and keep them in a safe place for future reference.
Use the unit only as described in this instruction manual.
This is a home medical device designed to administer nebulizer medications prescribed or recommended by your physician. Please visit www.my.nuvita.com to see the entire range of NUVITA products.

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



Assembly diagram

**A Aerosoltherapy unit (main unit)**
A1 - On/off switch
A2 - Air inlet
A3 - Air filter
A4 - Nebuliser holder
A5 - Carrying handle
A6 - Power cord

**B Connection tube**
(main unit / nebuliser)

**C Accessories**
C1 - RF6 basic2 nebuliser
C1.1 - Lower part
C1.2 - Complete nozzle
C1.3 - Upper part
C1.4 - Cap
C2 - Mouthpiece
C3 - Adult nose piece
C4 – Adult mask
C5 - Pediatric mask

**D Convenient, roomy carrying bag**

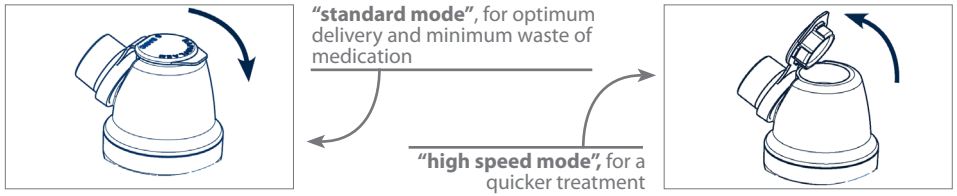
## IMPORTANT SAFEGUARDS

• Before using the unit for the fi rst time, and periodically throughout its life, check the power supply cord for any damage; if you detect any damage, do not plug it in. Take the appliance immediately to an authorised service centre or your local dealer.
•When used very frequently, we recommend that the nebuliser be replaced every 6 months (or earlier if it becomes clogged), in order to guarantee the 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.
• 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.
•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.
• 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 in the device.
• Do not obstruct the air slots 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 slots before each use.
•Do not place any objects inside the air slots.
• 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.

## INSTRUCTIONS FOR USE

**Before each use, the nebuliser and accessories should be cleaned according to the instructions in the section"CLEANING, DISINFECTION, AND MAINTENANCE". A personal use of the nebuliser and its accessories is recommended in order to avoid any risks of infection.**

1. Insert the power cord (A6) into a power socket corresponding to the voltage of the device. This must be positioned so that it is not difficult to make the disconnection from the mains.
2. Open the nebuliser by turning the upper part (C1.3) counterclockwise.
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 the accessories as shown in the "Assembly diagram". The cap (C1.4) provided with the nebuliser RF6 basic2 makes it possible to deliver the medication in 2 modes:



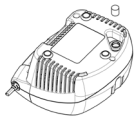

5. Start the unit by turning the switch on (A1).
6. When the treatment is finished, turn off and unplug the unit.
7. It may happen that during the use of the nebuliser visible humidity deposits form in the connection tube(B): disconnect the tube from the nebuliser and let it dry using the compressor air fl ow in order to reduce any risks of infection between users.

## CLEANING, DISENFECTION, AND MAINTENANCE

*Before undertaking any cleaning operation, switch off and unplug the unit.*
Before and after each use, clean the nebulizer and accessories according to the instructions below. It is recommended that each person use their own nebulizer and accessories to prevent risk of infection due to contamination.
Open the nebulizer by turning the top piece (C1.3) anticlockwise. Disconnect the nozzle by pressing as indicated by the 2 arrows in the "Assembly diagram sect. C1.
**Washing**: Wash accessories (C) under potable water with a mild dish soap (non abrasive) or in a dishwasher using the hot cycle.For the device (A) and outer tube surface (B), use only a cloth dampened with anti-bacterial detergent (non abrasive and free from any kind of solvent).
Drying: After washing the accessories, shake off any excess water and place on a paper towel to dry, or dry the accessories with a warm air flow (e.g. using a hair dryer).
Disinfection (method A): (except for the connection tube) soak in a solution of 60% water and 40% white vinegar. Rinse thoroughly with potable water.
Disinfection (method B): boil in water for 20 minutes (except connection tube); for this method you should use distilled or demineralized water to prevent limescale deposits.

## AIR FILTERING

The unit is equipped with an air filter (A3) which should be replaced when dirty or when its colour changes. To replace the filter take it out by pulling it as shown in figure. The filter is designed to remain fixed in its housing.



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|---|---|---|
| Class II unit | | Type B applied part |
| Follow the operating instructions | | Alternating current |
| I Switch "ON" | When you shut off the device, the switch will interrupt the compressor function only on one of the two power phases | Do not use device while taking a bath or shower |
| O Switch "OFF" | | |
| In conformità a: Norma Europea EN 10993-1 "Valutazione Biologica dei dispositivi medici"ed alla Direttiva Europea 93/42/EEC "Dispositivi Medici" | | CE 0051 CE mark for medical devices ref. Dir. 93/42 EEC and subsequent amendments |
| | | BAUART GEPRÜFT TYPE APPROVED TÜV Certification ref. EN 60601-1 3rd Ed. |

## TECHNICAL FEATURES

| **Unit Mod. 5020** | |
|---|---|
| Power supply: | 230V~ 50Hz 130VA |
| Max pressure: | 1.8 ± 0.3 |
| Compressor air output: | 9 LPM approx |
| Sound level (at 1 m): | 54 dB (A) approx |
| Operation: | continuos |
| Operating conditions: | Temperature: min 10°C; max 40°C<br>RH Air humidity: min 10%; max 95%<br>Atmospheric pressure: min 690Pa; max 106KPa |
| Storage conditions: | Temperature: min -25°C; max 70°C<br>RH Air humidity: min 10%; max 95%<br>Atmospheric pressure: min 69KPa; max 106KPa |
| In compliance with: Dir. 93/42/EEC | CE 0051 |
| Safety Certifications:<br>(for Mod. P0111EM F400) | BAUART GEPRÜFT TYPE APPROVED |
| Dimensions (W)x(D)x(H) | 16,8x17,2x10,7 cm |
| Weight: | 1,2 Kg |

## APPLIED PARTS

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|---|---|
| Type B applied parts are: | Patient accessories (C3,C2,C4 ,C5) |
| RF6 basic2 nebuliser | |
| Medication minimum capacity: | 2 ml |
| Medication maximum capacity: | 8 ml |
| Operating pressure (with neb.): | 0,65 bar approx. |

| | |
|---|---|
| Delivery: | 0,32 ml/min approx. Mod. High speed<br>0,25 ml/min approx. mod. Standard |
| MMAD: | 4 µm MMAD - Mod. High speed<br>3,8 µm MMAD - Mod. Standard |
| Breathable fraction < 5 µm (FPF): | 62 % Mod. Standard<br>63 % Mod. High speed |

(1) data detected according to Flaem I29-P07.5 internal procedure
(2) In vitro characterization certified by TÜV Rheinland LGA Products GmbH - Germany in compliance with the new European Standard for aerosol therapy units, Standard EN 13544-1, ANNEX CC. Further details are available on request.

Disposal of device:In conformity with Directive 2002/96/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 art. 50 and subsequent amendments of Legislative Decree no. 22/1997.

**Electromagnetic compatibility**
This device has been designed to meet the current requirements for electromagnetic compatibility (EN 60601-1-2:2007 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. Potential risk of electromagnetic interference with other devices, in particular with other devices for analysis and treatment I Radio and mobile or portable RF communications devices (mobile phones or wireless connections) may interfere with the operation of electromedical devices. For additional information visit the website www.my-nuvita.com.The Manufacturer reserves the right to make technical and functional changes to the product without notice.

## WARRANTY - TERMS AND CONDITIONS

This product benefits of a warranty of 24 months on material and manufacturing defects, starting from the date of purchase (see sales slip).
The warranty of 24 months does not include damages caused by the usual use of parties identified as "consumable" (e.g., batteries, brush heads or parts subject to usury).
The legal guarantee of 24 months is void if:
1.The product has undergone aesthetic damage due to improper use not in accordance with instructions in the manual.
2.This product has been modified and/or tampered with.
3.The cause of the failure was due to poor maintenance of the individual components and/or accessories and/or supplies (e.g. oxidation and/or scaling due to the retention of water or other liquids, sediment blocking the sensor, leak of corrosive liquid from batteries).
The following is excluded from the legal guarantee of 24 months:
1.Costs related to replacements and/or repair of parts subject to wear or costs for ordinary maintenance of the product.
2.The costs and risks involved in transporting the product to and from the store where you purchased or otherwise authorized collection centre to receive the products under warranty.
3.Damage caused by or resulting from improper installation or improper use not in accordance with the directions in the instruction manual.
4.Damage due to natural disasters, accidental events or adverse conditions not compatible with the product.
5.Defects that have a negligible effect on product performance.
The manufacturer, distributor and all the parties involved in the sale do not assume any liability for losses and economic damage from any malfunction of the product. In accordance with current regulations the manufacturer, distributor and all the parties involved in the sale are not responding in any case for damages, including direct, indirect ones, loss of net income, loss of savings and additional damage and other details consequences going beyond the damage caused by the breach of warranty, contract, strict liability, wrongdoing or due to other causes, resulting from the use or inability to use the product and/or paper and electronic documents, including the lack of service.

For further information on the help service visit the website www.nuvitababy.com