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CE 1639

IB NEB 210 EN 2421
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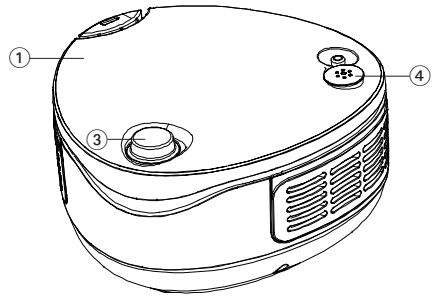
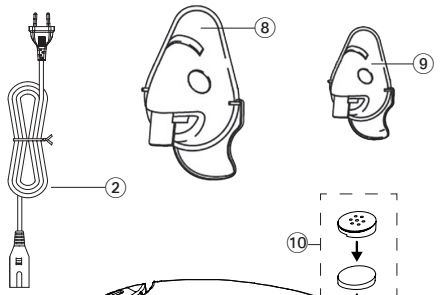
microlife®

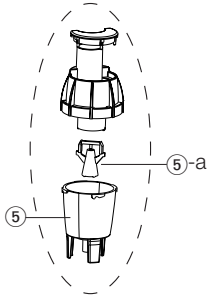
NEB210

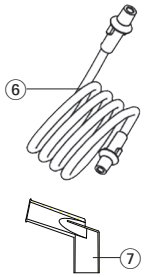
Compressor Nebuliser

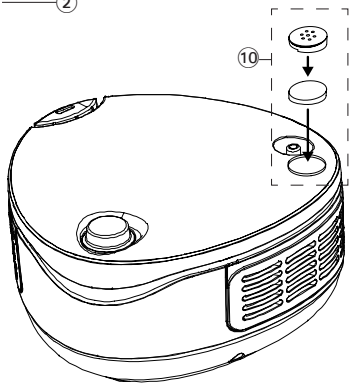
EN → 1

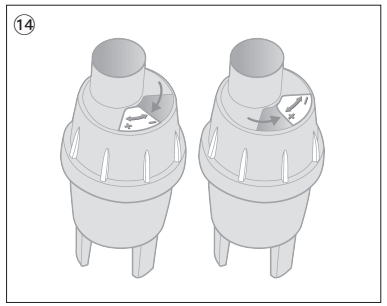


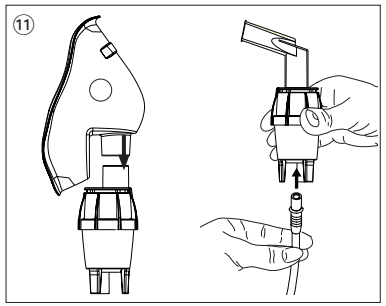


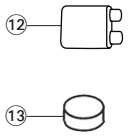












Name of Purchaser _____

Serial Number _____

Date of Purchase _____

Specialist Dealer _____

microlife®

1 Piston compressor
2 Power lead
3 ON/OFF Switch
4 Air filter compartment
5 Nebuliser
-a: Vaporiser head
6 Air tube
7 Mouthpiece
8 Adult face mask
9 Child face mask
AT Replacing air filter
AK Assembling nebuliser kit
AL Nose piece
AM Air filter
AN Adjustable flow rate

Intended use:
This nebuliser is an aerosol therapy system suitable for domestic use.
This nebuliser is designed for the production of compressed air to operate a nebuliser kit for the production of medical aerosol for respiratory disorders.
Patient population: The device is intended for use with children from 2 years old, adolescent and adult patients.
Intended users: The use of the device does not require a specific knowledge or professional ability. The patient is the intended operator except in case of child and patient that required special assistance.

Dear Customer,
This nebuliser is an aerosol therapy system suitable for domestic use. This device is used for the nebulisation of liquids and liquid medication (aerosols) and for the treatment of the upper and lower respiratory tract.
If you have any questions, problems or want to order spare parts please contact your local Microlife-Customer Service. Your dealer or pharmacy will be able to give you the address of the Microlife dealer in your country. Alternatively, visit the internet at www.microlife-asiapacific.com where you will find a wealth of invaluable infor mation on our products.
Stay healthy – Microlife AG!

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1. Explanation of Symbols

This product is subject to European Directive 2012/19/EU on waste electrical and electronic equipment and is marked accordingly. Never dispose of electronic devices with household waste. Please seek out information about the local regulations with regard to the correct disposal of electrical and electronic products. Correct disposal helps to protect the environment and human health.

Read the instructions carefully before using this device.

Type BF applied part

Class II equipment

SN Serial number

REF Reference number

Manufacturer

| ON

○ OFF

IP21 Protection against solid foreign objects and harmful effects due to the ingress of water

EC REP Authorized representative in the European Community

 Distributor

 Caution

 Single patient multiple use (for accessories only)

 Humidity limitation

 Temperature limitation

 Ambient pressure limitation

CE 1639 CE Marking of Conformity

2. Important Safety Instructions

- Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.
- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- Retain instructions in a safe place for future reference.
- Do not operate the unit in presence of any anesthetic mixture inflammable with oxygen or nitrogen protoxide.
- This device is designed to nebulise solution and suspension liquids.
- This nebulizing system is not suitable for use in anaesthetic breathing system or a ventilator breathing system.
- This device is not suitable for anaesthesia and lung ventilation.
- This device should only be used with original accessories as shown in these instructions.
- Do not use this device if you think it is damaged or notice anything unusual.
- Never open this device.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical Specifications» section.
- Protect it from:
  - water and moisture
  - extreme temperatures
  - impact and dropping
  - contamination and dust
  - direct sunlight
  - heat and cold
- Comply with the safety regulations concerning the electrical devices and in particular:
  - Never touch the device with wet or moist hands.
  - Place the device on a stable and horizontal surface during its operation.
  - Do not pull the power cord or the device itself to unplug it from the power socket.
  - The power plug is a separate element from the grid power; keep the plug accessible when the device is in use.
- Before plugging in the device, make sure that the electrical rating, shown on the rating plate on the bottom of the unit, corresponds to the mains rating.
- In case the power plug provided with the device does not fit your wall socket, contact qualified personnel for a replacement plug with that of a suitable one. In general, the use of adapters, simple or multiple, and/or extension cables is not recommended. If their use is indispensable, it is necessary to use types complying with safety regulations, paying attention that they do not exceed the maximum power limits, indicated on adapters and extension cables.
- Do not leave the unit plugged in when not in use; unplug the device from the wall socket when it is not in operation.
- The installation must be carried out according to the instructions of the manufacturer. An improper installation can cause damage to persons, animals or objects, for which the manufacturer cannot be held responsible.

- Do not replace the power lead of this device. In case of a power lead damage, contact a technical service center authorized by the manufacturer for its replacement.
- The power supply cord should always be fully unwound in order to prevent dangerous overheating.
- Before performing any maintenance or cleaning operation, turn off the device and disconnect the plug from the main supply.
- Only use the medication prescribed for you by your doctor and follow your doctor's instructions with regard to dosage, duration and frequency of the therapy.
- Depending on the pathology, only use the treatment that is recommended by your doctor.
- Only use the nose piece if expressly indicated by your doctor, paying special attention NEVER to introduce the bifurcations into the nose, but only positioning them as close as possible.
- Check in the medicine instruction leaflet for possible contraindications for use with common aerosol therapy systems.
- Do not position the equipment so that it is difficult to operate the disconnection device.
- Nebuliser and accessories are single patient use. Device is multi-patient use.
- Never bend the nebuliser over 60°.
- Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations. Keep a minimum distance of 3.3 m from such devices when using this device.

Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed. Be aware of the risk of strangulation in case this device is supplied with cables or tubes.

⚠ Use of this device is not intended as a substitute for a consultation with your doctor.

3. Preparation and Usage of this Device

Prior to using the device for the first time, we recommend cleaning it as described in the section «Cleaning and Disinfecting».

1. Assemble the nebuliser kit ⑪. Ensure that all parts are complete.
2. Fill the nebuliser with the inhalation solution as per your doctor's instructions. Ensure that you do not exceed the maximum level.
3. Connect the nebuliser with the air tube ⑥ to the compressor ① and plug the power lead ② into the socket (230V 50 Hz AC).
4. To start the treatment, set ON/OFF switch ③ into the «**I**» position.
   - The mouthpiece gives you a better drug delivery to the lungs.
   - Choose between adult ⑧ or child face mask ⑨ and make sure that it encloses the mouth and nose area completely.
   - Use all accessories including the nose piece ⑫ as prescribed by your doctor.
5. During inhalation, sit upright and relaxed at a table and not in an armchair, in order to avoid compressing your respiratory airways and impairing the treatment effectiveness. **Do not lie down while inhaling.** Stop inhalation if you feel unwell.
6. After completing the inhalation period recommended by your doctor, switch the ON/OFF switch ③ to position «**O**» to turn off the device and unplug it from the socket.
7. Empty the remaining medication from the nebuliser and clean the device as described in the section «Cleaning and Disinfecting».

☞ **This device was designed for intermittent use of 30 min. On / 30 min. Off.** Switch off the device after 30 min. use and wait for another 30 min. before you resume treatment.

☞ The device requires no calibration.

⚠ No modification to the device is permitted.

4. Cleaning and Disinfecting

Thoroughly clean all components to remove medication residuals and possible impurities after each treatment.
Use a soft and dry cloth with non-abrasive cleaners to clean the compressor.

⚠ Make sure that the internal parts of the device are not in contact with liquids and that the power plug is disconnected.

Cleaning and disinfecting of the accessories
Follow carefully the cleaning and disinfecting instructions of the accessories as they are very important to the performance of the device and success of the therapy.

Before and after each treatment
Disassemble the nebuliser ⑤ by turning the top counterclockwise and remove the medicine conduction cone. Wash the components

of the disassembled nebuliser, the mouthpiece 7 and the nose piece AL by using tap water; dip in boiling water for 5 minutes. Reassemble the nebuliser components and connect it to the air tube connector, switch the device on and let it work for 10-15 minutes.

☞ Wash masks and air tube with warm water.

☞ Only use cold disinfecting liquids following the manufacturer's instructions.

⚠ Do not boil nor autoclave the air tube and masks.

5. Maintenance, Care, and Service

Order all spare parts from your dealer or pharmacist, or contact Microlife-Service

Replacement of the nebuliser

Replace the nebuliser 5 after a long period of inactivity, in cases where it shows deformities, breakage, or when the vaporiser head 5 -a is obstructed by dry medicine, dust, etc. We recommend to replace the nebuliser after a period between 6 months and 1 year depending on the usage.

⚠ Only use original nebulisers!

Replacement of the air filter

In normal conditions of use, the air filter AMmust be replaced approximately after 200 working hours or after each year. We recommend to periodically check the air filter (10 - 12 treatments) and if the filter shows a grey or brown colour or is wet, replace it. Extract the filter and replace it with a new one.

☞ Do not try to clean the filter for reusing it.

☞ The air filter shall not be serviced or maintained while in use with a patient.

⚠ Only use original filters! Do not use the device without filter!

6. Malfunctions and Actions to take

The device cannot be switched on

- Ensure the power lead 2 is correctly plugged into the socket.
- Ensure the ON/OFF switch 3 is in the position «**I**».
- Make sure that the device has been operating within operating limits indicated in this manual (30 min On / 30 min Off).

The nebuliser functions poorly or not at all

- Ensure the air tube 6 is correctly connected at both ends.
- Ensure the air tube is not squashed, bent, dirty or blocked. If necessary, replace with a new one.
- Ensure the nebuliser 5 is fully assembled and the vaporiser head 5 -a is placed correctly and not obstructed.
- Ensure the required medication has been added.

7. Guarantee

This device is covered by a **3 year guarantee** from the date of purchase. During this guarantee period, at our discretion, Microlife will replace the defective product free of charge.
Opening or altering the device invalidates the guarantee.
The following items are excluded from the guarantee:

- Transport costs and risks of transport.
- Damage caused by incorrect application or non-compliance with the instructions for use.
- Damage caused by accident or misuse.
- Packaging/storage material and instructions for use.
- Regular checks and maintenance.
- Accessories and wearing parts: Nebuliser, masks, mouthpiece, nose piece, tube, filters, nasal washer.

Should guarantee service be required, please contact the dealer from where the product was purchased, or your local Microlife service. You may contact your local Microlife service through our website:
www.microlife-asiapacific.com/support
Compensation is limited to the value of the product. The guarantee will be granted if the complete product is returned with the original invoice. Repair or replacement within guarantee does not prolong or renew the guarantee period. The legal claims and rights of consumers are not limited by this guarantee.

8. Technical Specifications

Model:	NEB 210
Aerosol performances according to EN13544-1:2009 based on adult ventilatory pattern with sodium fluoride (NaF):	
Nebulisation rate:	0.4 ml/min. (NaCl 0.9%)
Aerosol output:	1.1 ml
Aerosol output rate:	0.13 ml/min.
Residual Volume:	≤ 0.5 ml
Particle size (MMAD):	≤ 2.08 µm
GSD (geometric standard deviation):	1.87 µm
RF (respirable fraction %, 0.5 - 5 µm):	95.8 %
Large particle range (> 5 µm):	4.2 %
Maximum air pressure:	2.41 bar
Operating air flow:	5~8 l/min.
Acoustic noise level:	51.5 dBA
Power source:	230V 50 Hz AC
Current:	≤ 700mA
Power lead length:	1.8 m
Nebuliser capacity:	min. 2 ml; max. 6 ml
Operating limits:	30 min. On / 30 min. Off
Operating conditions:	10 - 40 °C / 50 - 104 °F 10-95 % relative maximum humidity 700 - 1060 hPa Atmospheric pressure
Storage and shipping conditions:	-20 - +60 °C / -4 - +140 °F 10-95 % relative maximum humidity 700 - 1060 hPa Atmospheric pressure
Weight:	approx. 1200 g
Dimensions:	160 x 161 x 90 mm
IP Class:	IP21
Reference to standards:	EN 13544-1; EN 60601-1; EN 60601-2; EN 60601-1-6; IEC 60601-1-11
Expected service life:	1000 hours

Class II device as regards protection against electric shocks.
Nebuliser, mouthpiece and masks are type BF applied parts.

⚠ The technical specifications may change without prior notice.

Please report any serious incident that has occurred in relation to the device, injury or adverse event to the local competent authority and to the manufacturer or to the european authorised representative (EC REP).