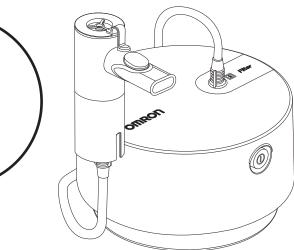
OMRON



C28P (NE-C105-UK) Instruction Manual

IM-NE-C105-UK-01-03/2020 3A4348 rev.00 Issue Date: 2020-09-28

All for Healthcare

Thank you for purchasing the OMRON C28P nebulizer.

This product was developed in conjunction with respiratory therapists for the successful treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), chronic bronchitis, allergies and other respiratory disorders. This is a medical device. Operate the device only as instructed by your doctor and/or respiratory therapist.

Intended use

Medical Purpose:

This product is intended to be used for inhaling medication for respiratory

Intended User:

- · Legally certified medical experts, such as doctor, nurse and therapist or healthcare personnel or patient under the guidance of qualified medical
- The user should also be capable of understanding the general operation of the C28P nebulizer and the content of this instruction manual.

Intended Patients:

Persons who suffer from respiratory disorders and require inhalation of medications

Environment:

This product is intended for use in a medical facility, such as hospital, clinic and doctor's office, and in general household

Durable period:

Durable periods are as follows, provided the product is used to nebulize 3 times a day for 10 minutes each time at room temperature (23°C). Durable period may vary depending on usage environment.

> Compressor (Main unit): 7.5 years Power cord: 7.5 years

Nebulizer Kit / Mouthpiece /

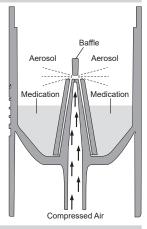
Child Mask / Adult Mask /

Air Tube / Adapter: Air Filter 60 days

Frequent usage of the product may shorten the durable period.

How the nebulizer kit works

The medication that is pumped up through the medication channel is mixed with compressed air which is generated by a compressor pump. The compressed air mixed with medication is turned into fine particles and sprayed when in contact with the baffle.



Nebulizer Kit with Advanced Valve Technology (AVT)

The C28P nebulizer is equipped with a breath-enhanced valve system which allows the maximum amount of medication to be inhaled by the patient. It optimizes the flow of medication during inhalation and reduces medication loss during exhalation.

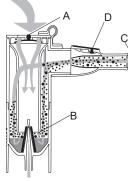
of the inhaled medication is optimized.

Inhalation phase

During inhalation, the inhalation valve (A) opens and air enters the nebulizer.

The air is mixed with the generated aerosol (B) and inhaled through the mouthpiece by the patient (C).

In this phase the exhalation valve (D) remains closed preventing aerosol from being wasted.



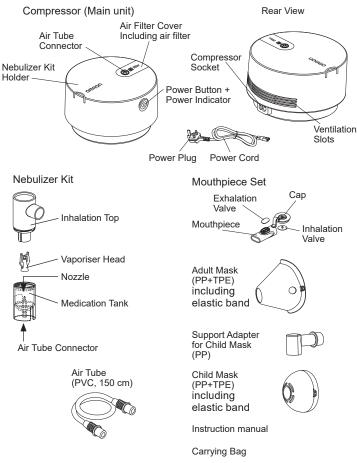
Exhalation phase

When exhaling through the mouthpiece, the inhalation valve (A) of the nebulizer closes, preventing aerosol to leave the nebulizer. The aerosol generated remains in the nebulizer and becomes available for the next inhalation phase

The exhaled air leaves the mouthpiece through the exhalation valve (D).



Know your unit



Important safety instructions

A Read the instructions carefully before use.

Warning:

Use the device only as inhalator for the apeutic purposes. Any other use is improper and may be dangerous. The manufacturer is not liable for improper uses.

Spare Air Filters x 5

- Do not use in anaesthetic or ventilator breathing circuits.
- Always disconnect the power plug after use.
- Do not to cover the ventilation slots during use. The compressor could get hot and there is a possible risk of a burn if touched.
- The compressor and power plug are not waterproof. Do not spill water or other liquids on these parts. If liquid does spill on these parts, immediately unplug the power plug and wipe off the liquid. Do not attempt to repair the device. See "Troubleshooting" section.
- Keep the device out of reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- 8. Provide close supervision when this device is used by, on, or near children or persons with limited capabilities.
- For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist
- **10.** This product should not be used on patients, who are unconscious or are not breathing spontaneously. 11. After finishing the treatment remember to disconnect the air tube from
- the nebulizer kit and from the compressor. 12. In view of their length, the power cord and air tube could constitute a
- strangulation hazard. 13. Be sure to use the compressor at a place where the power plug is
- easily accessible during treatment 14. If you experience any allergic reactions or other difficulties during use. stop using the device immediately and consult your doctor.
- **15.** While using this device, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields is within 30 cm. This may result in degradation of performance of the device.
- 16. Do not use oils, decoctions and tinctures from herbs for inhalation in the compressor nebulizer.

How to use

- 1. Make sure that the power button is in OFF position. (The power indicator
- 2. Insert the power cord into the compressor socket and then plug the power plug into a power outlet.

 Note: Do not place the device in a location where it is difficult to

Lift the inhalation top out of the medication tank

3. Remove the inhalation top from the medication tank Rotate the inhalation top anti-clockwise.

disconnect the power cord

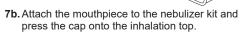
4. Verify that the vaporizer head is attached to the inhalation top



- 5. Add the correct amount of prescribed medication into the medication tank. Be sure to follow the instructions regarding the minimum and maximum fill volumes (see Technical data). If the nebulizer kit contains too little or too much medication; the nebulization, and thus also the treatment, will be greatly impaired.
- 6. Put the inhalation top back onto the medication tank.
- Lower the inhalation top on the medication tank. Rotate the inhalation top clockwise.

Using the mouthpiece

7a. Assemble the mouthpiece. Make sure that the valves are properly attached. Refer to this drawing.



inhalation and exhalation in order to get the maximal benefit by the valve system

who have particular needs of the mouthpiece. When using a mask, make sure the cap is removed from the inhalation top.

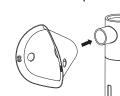


⚠ Caution:

In order to remove the mouthpiece from the nebulizer kit, it is important to detach first the cap from the inhalation top and then pull it out. Do not reverse this sequence!

Using the adult mask

7d. Attach the adult mask to the nebulizer kit.

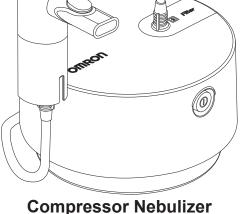


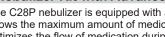
Using the child mask and adapter

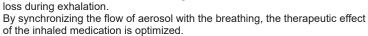
7e. Attach the child mask to the support adapter and connect it to the nebulizer kit.





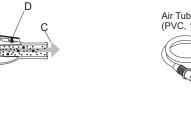




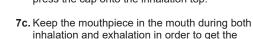


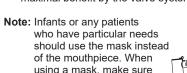
Note: Only using the mouthpiece enables the synchronized functioning of the

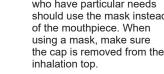




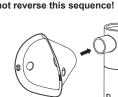




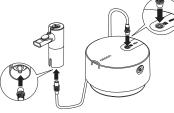








8. Attach the air tube. While twisting the air tube plug slightly, push it firmly into the air tube connector.



9. Hold the nebulizer kit as indicated on the right. Follow the instructions of your doctor or respiratory therapist.



⚠ Caution:

Do not tilt the nebulizer kit at an angle of greater than 30 degrees in all directions. Medication may flow into the mouth or it may result in ineffective nebulization

- 10. Power on the compressor by pressing the power button; the blue power indicator is lit. As the compressor starts, nebulization begins, and aerosol is generated. Gently inhale the medication. Exhale through the mouthpiece
- 11. When treatment is completed, press the power button again to power off the device. Then unplug the compressor from the power outlet.

Cleaning and daily disinfecting

Observe the rules below when cleaning or disinfecting parts. Failure to observe these rules may result in damage, inefficient nebulization or

Carefully wash your hands before cleaning and disinfecting the nebulizer

Clean and disinfect the Nebulizer Kit and its parts and accessories (Masks, Mouthpiece and Adapter) before using them as follows:

- the first time after purchase (cleaning and disinfection)
- if the device has not been used for a long period of time (cleaning and disinfection)
- if another person uses the same device (cleaning and disinfection)
- after each use (cleaning)
- after the last treatment of the day (cleaning and disinfection)

Cleaning the Nebulizer Kit, Masks, Mouthpiece (including all parts) and Adapter:

Fully disassemble the nebulizer kit. Remove the valves from the mouthpiece. Wash the parts in warm water and mild, neutral detergent. Rinse them thoroughly with clean hot tap water, gently tap to remove excess water and allow to air dry in a clean place. It is advisable to replace the Nebulizer Kit and Mouthpiece after some 100 to 120 treatments or after about 20 boiling

• Cleaning the Compressor:

Make sure that the power plug is unplugged from the power outlet. Wipe clean with a soft cloth moistened with water or mild, neutral detergent.

• Removing condensation from the Air Tube:

If moisture remains in the air tube, follow the procedure described below. Make sure that the air tube is connected to the compressor. Disconnect the air tube from the nebulizer kit. Turn on the compressor and dry the air tube by passing air through it.

• Disinfecting the Nebulizer Kit, Masks, Mouthpiece (including all parts) and Adapter:

If the parts are heavily stained, replace them with new ones. The Nebulizer Kit, Masks, Mouthpiece (including all parts) and Adapter can be disinfected by using a chemical disinfectant such as ethanol, sodium hypochlorite (Milton), following product instructions and rinsing off with clean warm water. Leave to air-dry.

Note: Never clean with benzene, thinner or a flammable chemical. The (non-latex) elastic bands cannot be disinfected. Remove them when disinfecting the masks.

• Boiling:

The Nebulizer Kit, Mouthpiece (including all parts), Masks and Adapter can also be disinfected by boiling between 15 to 20 minutes in plenty of water. After boiling, carefully remove the parts, shake off excess water and allow to air-dry in a clean environment

Note: Do not boil the Air Tube

Changing the air filter

If the air filter has changed color, or has been used for more than 60 days, replace it with a new one. To purchase the filters - see Other Optional/ Replacement Parts section.

Remove the air filter cover using a flat screwdriver as shown in figure; remove the filter and fit the new filter as shown.

Put the air filter cover back in place.

Note: Do not wash or clean the air filter. If the air filter becomes wet, replace it.

Damp air filters can cause blockages



Technical data

Product Category: Aerosoltherapy Equipment Compressor Nebulizer **Product Description:** C28P (NE-C105-UK) Model (code): Rating: 230V ~50Hz

Power Consumption: 140VA Operating Mode: Continuous Use Operating Temperature/ +5°C to +40°C

Humidity/Air Pressure: 15% to 85%RH / 700 to 1060 hPa Storage and Transport -20°C to +60°C / 5% to 95%RH /

Temperature/Humidity/ 500 to 1060 hPa

Air Pressure:

Classifications: Type BF (Applied part): Mouthpiece and

Class II (Protection against electric shock)

IP Classification: IP21

Approx. 1.3 kg (compressor only) Weight of Compressor: Dimensions of

Approx. Ø 180 x 104 (H) mm Compressor:

Contents: Compressor, Power Cord with UK Plug, Nebulizer Kit, Air Tube (150 cm), Mouthpiece Set, Adapter, Adult Mask, Child Mask, Carrying

Bag, 5 pcs Spare Air Filters, Instruction Manual

2 ml minimum - 10 ml maximum Appropriate Medication Quantities:

Residual volume of

medication:

Approx. 0.7 ml

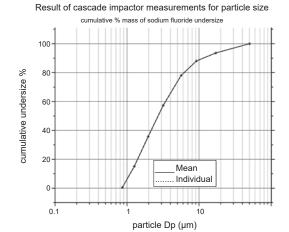
Sound: Noise level Approx. 55 dB (at 1 m distance)

Particle Size (MMAD): Approx. 2.65 µm Aerosol Output Approx. 0.7 ml (2 ml, 1% NaF):

Aerosol Output Rate (2 ml. 1% NaF):

Approx. 0.12 ml/min

MMAD = Mass Median Aerodynamic Diameter





Symbols description Need for the user to **%** įį Humidity limitation consult the instructions for use Applied part – Type BF Atmospheric pressure Degree of protection (\$• against electric shock limitation (leakage current) Class II Protection against Temperature limitation electric shock Ingress protection Power ON/OFF IP XX degree provided by ① (push-push) IEČ 60529

MD

M

Alternating current

Date of Manufacture

Medical Device

General Notes:

 ϵ

LOT

SN

CE Marking

LOT number

Serial number

- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. The compressor is protected against solid foreign objects of 12 mm diameter and greater such as a finger, and against vertically falling water drops which may cause issues during a normal operation
- Subject to technical modification without prior notice.
- The device may not work if the temperature and voltage conditions are different to those defined in the specifications.
- Performance may vary with drugs such as suspensions or high viscosity.
 See drug supplier's data sheet for further details.

Troubleshooting

In case of any of the below problems occur during use, first check that no other electrical device is within 30 cm. If the problem persists, please refer to the table below

The device does not switch on

- Check that the power plug is properly fitted to the power outlet and the power cord is connected to the socket of the compressor
- Make sure the power button is in on position. The device switches on but does not nebulize
- Make sure the vaporizer head is attached to the inhalation top of the nebulizer kit
- · Make sure the air tube is not squashed or crooked.
- · Check the air filter for blockage and dirt. Replace if necessary.
- Check that sufficient amount of medication has been put into the nebulizer

The device suddenly stops working during operation.

- · The thermal cut-out has shut the device down for one of the following reasons: - the device was working in an environment with temperatures higher than
- the ventilation slots were covered.

Do not attempt to repair the device. Do not open and/or tamper with the device. No parts of the device are user serviceable. Return the device to an authorized OMRON retail outlet or distributor.

Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you the highest level of comfort, provided it is properly operated and maintained as described in the instruction manual. This product is guaranteed by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product is guaranteed by OMRON. During this period of guarantee OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts. The guarantee does not cover any of the following: a. Transport costs and risks of transport.

- b. Costs for repairs and/or defects resulting from repairs done by unauthorized persons.
- c. Periodic check-ups and maintenance.
- d. Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly guaranteed above.
- e. Costs arising due to non-acceptance of a claim (those will be charged for).
- f. Damages of any kind including personal caused accidentally or from misuse.

Should guarantee service be required please apply to the dealer whom the product was purchased from or an authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised

Repair or replacement under the quarantee does not give rise to any extension or renewal of the guarantee period

The guarantee will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer OMRON reserves the right to refuse the guarantee service if any unclear information has been given

Optional Medical Accessories

Product Description	Model
Nebulizer Kit	NEB6026
Air Tube	NEB6016
Mouthpiece Set (Contents: Mouthpiece with cap, Exhalation Valve, Inhalation Valve)	NEB6027
Child Mask (including elastic band)	NEB6028
Adult Mask (including elastic band)	NEB6029
Support Adapter for Child Mask	NEB6030
Nasal shower	NEB6014

Other Optional/Replacement Parts

Product Description	Model
Power Cord with EU Plug	3AC459
Power Cord with UK Plug	3AC460
Air Filter Set (Contents: 5 pieces)	3AC458

Important information regarding Electro Magnetic Compatibility (EMC) This device manufactured by 3A HEALTH CARE S.r.l. conforms to

EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual or at www.omron-healthcare.com.



DISPOSAL PROCEDURE (Dir. 2012/19/EU-WEEE)

This product is not to be treated as regular household waste but must be returned to a collection point for recycling electric and electronic devices. Further information is available from your municipality, your municipality's waste disposal services, or the retailer where you purchased your product.

Manufacturer	3A HEALTH CARE S.r.I. Via Marziale Cerutti, 90F/G 25017 Lonato del Garda (BS), Italy		
Distributor	OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com		
Subsidiary	Importer in the United Kingdom and UK responsible person	OMRON HEALTHCARE UK LTD. Opal Drive, Fox Milne, Milton Keynes, MK15 0DG, UK www.omron-healthcare.com	

Made in Italy