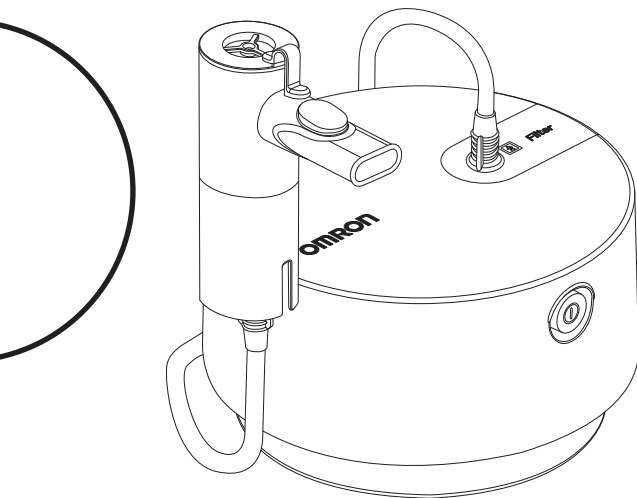




Compressor Nebulizer C28P (NE-C105-E) Instruction Manual

EN

FR

DE

IT

ES

NL

RU

TR

AR

IM-NE-C105-E-02-11/2022
3A4325 rev.01

Issue Date/Date de publication/Ausgabedatum/
Data di pubblicazione/Fecha de publicación/ : 2022-11-16
Uitgiftedatum/Дата выпуска/Yayın Tarihi/تاريخ الإصدار

Table of Contents

Intended use	3
How the nebulizer kit works	4
Nebulizer Kit with Advanced Valve Technology (AVT).....	5
Know your unit	6
Important safety instructions	7
How to use	8
Cleaning and disinfecting	12
Changing the air filter	13
Technical data	14
Troubleshooting.....	17
Warranty.....	18
Optional Medical Accessories	19
Other Optional/Replacement Parts	19

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 disorders. The compressor is intended for multi-patient reuse while the nebulizer kit and its attachments are single-patient reuse.

Intended User:

- Legally certified medical experts, such as doctor, nurse and therapist or healthcare personnel or patient under the guidance of qualified medical experts.
- 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 of all ages 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.

EN

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.

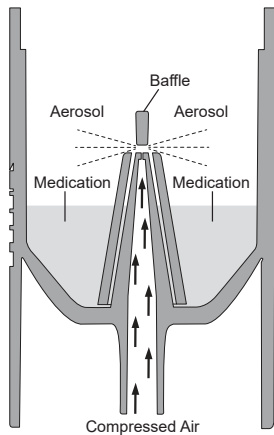
Compressor (Main unit):	7.5 years
Power cord:	7.5 years
Nebulizer Kit / Mouthpiece / Child Mask / Adult Mask / Air Tube / Adapter:	1 year
Air Filter:	60 days

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 on the vaporiser head.



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.

By synchronizing the flow of aerosol with the breathing, the therapeutic effect of the inhaled medication is optimized.

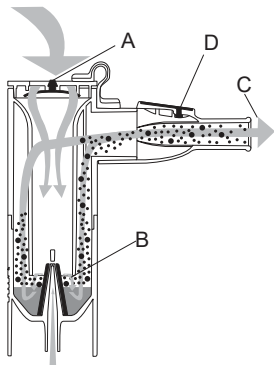
Note: Only using the mouthpiece enables the synchronized functioning of the nebulizer!

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).

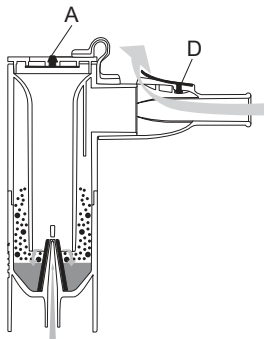
In this phase the exhalation valve (D) remains closed preventing aerosol from being wasted.



EN

Exhalation phase

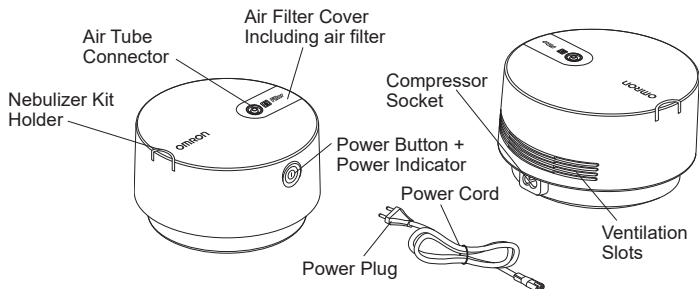
When exhaling through the mouthpiece, the inhalation valve (A) of the nebulizer closes, preventing aerosol to leave the nebulizer. The aerosol generated remains in the nebulizer and becomes available for the next inhalation phase. The exhaled air leaves the mouthpiece through the exhalation valve (D).



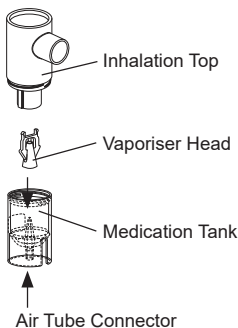
Know your unit

Compressor (Main unit)

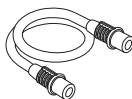
Rear View



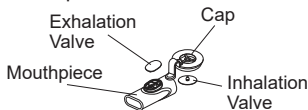
Nebulizer Kit



Air Tube (PVC, 150 cm)



Mouthpiece Set



Adult Mask (PP+TPE) including elastic band



Support Adapter for Child Mask (PP)



Child Mask (PP+TPE) including elastic band



Instruction manual

Carrying Bag

Spare Air Filters x 5

Important safety instructions

 Read the instructions carefully before use.

Warning:

1. Use the device only as inhalator for therapeutic purposes. Any other use is improper and may be dangerous. The manufacturer is not liable for improper uses.
2. Do not use in anaesthetic or ventilator breathing circuits.
3. Always disconnect the power plug after use and before cleaning.
4. 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.
5. 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.
6. Do not attempt to repair the device. See "Troubleshooting" section.
7. 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.
9. 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.
17. The nebulizer kit and its attachments are intended for use by a single patient. Do not use by multiple patients; Use separate accessories for each patient.
18. Clean the parts after each use and disinfect them once a week during normal use.

EN

How to use

1. Make sure that the power button is in OFF position (the power indicator is off) and the power plug is disconnected from the power outlet.

2. Remove the inhalation top from the medication tank.

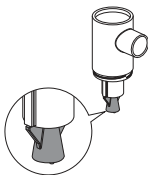
- 1) Rotate the inhalation top anti-clockwise.
- 2) Lift the inhalation top out of the medication tank.



3. 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.



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



5. Put the inhalation top back onto the medication tank.

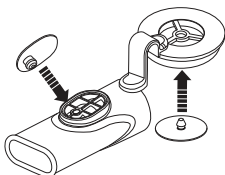
- 1) Lower the inhalation top on the medication tank.
- 2) Rotate the inhalation top clockwise.



Using the mouthpiece

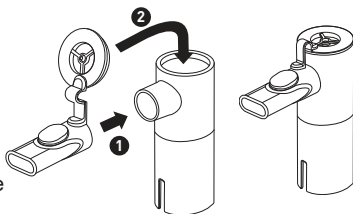
- 6a. Make sure that the valves are properly attached.

Refer to this drawing.



- 6b. Attach the mouthpiece to the nebulizer kit and press the cap onto the inhalation top.

- 6c. Keep the mouthpiece in the mouth during both inhalation and exhalation in order to get the maximal benefit by the valve system.

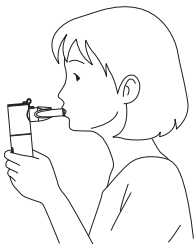


EN

Note: Infants or any patients who have particular needs should use the mask instead of the mouthpiece. When using a mask, make sure the cap is removed from the inhalation top.

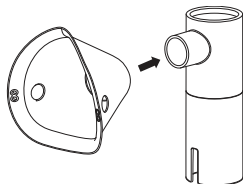
Caution:

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!**



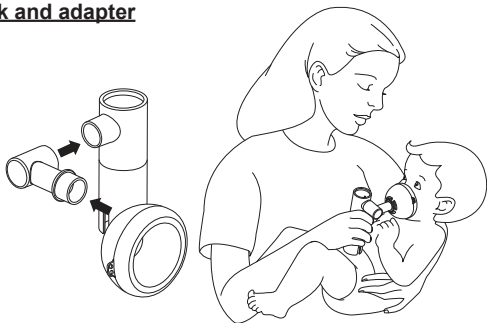
Using the adult mask

- 6d. Attach the adult mask to the nebulizer kit.

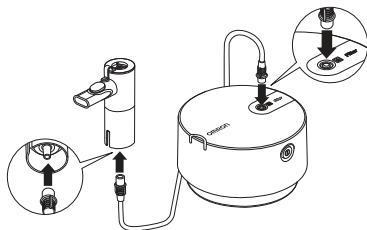


Using the child mask and adapter

- 6e. Attach the child mask to the support adapter and connect it to the nebulizer kit.



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



8. 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.

9. 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 disconnect the power cord.

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 and 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 disinfecting

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

Carefully wash your hands before cleaning and disinfecting the nebulizer parts.

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)
- after each use (cleaning)

Clean the parts after each use and disinfect them once a week during normal use.

• Cleaning the Nebulizer Kit, Masks, Mouthpiece and Adapter:

Fully disassemble the nebulizer kit. 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.

• 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 and Adapter:**

Disinfect the parts once a week. The parts are expected to withstand approx. 50 disinfection cycles. If the parts are heavily stained, replace them with new ones. The Nebulizer Kit, Masks, Mouthpiece 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, Masks and Adapter can also be disinfected by boiling at least 5 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.

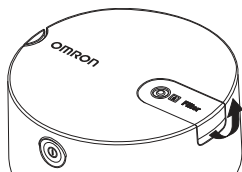
Remove the air filter cover. Pull up the air filter cover by hooking your finger on the groove, as shown in figure.

Remove the filter and fit the new filter as shown.

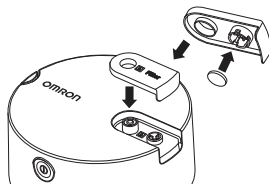
Put the air filter cover back in place.

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

Damp air filters can cause blockages



EN



Technical data

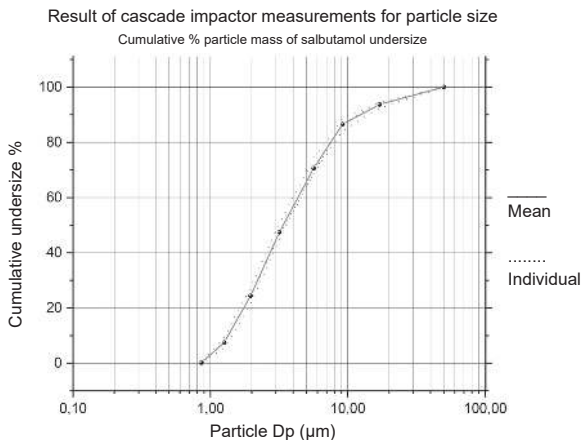
Product Category:	Aerosoltherapy Equipment
Product Description:	Compressor Nebulizer
Model (code):	C28P (NE-C105-E)
Rating:	230V ~50Hz
Power Consumption:	140VA (70W)
Operating Mode:	Continuous Use
Operating Temperature/ Humidity/Air Pressure:	+5°C to +40°C / 15% to 85%RH / 700 to 1060 hPa
Storage and Transport Temperature/Humidity/ Air Pressure:	-20°C to +60°C / 5% to 95%RH / 500 to 1060 hPa
Classifications:	Type BF (Applied part): Mouthpiece and Masks Class II (Protection against electric shock)
IP Classification:	IP21
Weight of Compressor:	Approx. 1.3 kg (compressor only)
Dimensions of Compressor:	Approx. Ø 180 x 104 (H) mm
Contents:	Compressor, Power Cord with EU Plug, Nebulizer Kit, Air Tube (150 cm), Mouthpiece Set, Adapter, Adult Mask, Child Mask, Carrying Bag, 5 pcs Spare Air Filters, Instruction Manual
Type of Medication Liquid:	Solution, Suspension
Appropriate Medication Quantities:	2 ml minimum - 10 ml maximum
Sound: Noise level (at 1 m distance)	Approx. 55 dB
Aerosol Output Rate**:	Approx. 0.12 ml/min
Percentage of fill volume emitted in 1 minute**:	Approx. 4%
Aerosol Output**:	Approx. 0.9 ml

Residual volume**:	Approx. 1.1 ml
Particle Size (MMAD)**:	Approx. 3.5 μm
GSD**:	Approx. 2.6
Respirable fraction < 5 μm **:	Approx. 64%
Aerosol fraction < 2 μm **:	Approx. 28%
Aerosol fraction from 2 μm to 5 μm **:	Approx. 36%
Aerosol fraction > 5 μm **:	Approx. 36%

MMAD = Mass Median Aerodynamic Diameter

GSD = Geometric standard deviation

** 3ml, 0.1% Salbutamol in 0.9% NaCl solution.



EN

Symbols description			
	Consult the instructions for use		Humidity limitation
	Need for the user to consult the instructions for use		Atmospheric pressure limitation
	Applied part – Type BF Degree of protection against electric shock (leakage current)		Temperature limitation
	Class II Protection against electric shock		Power ON/OFF (push-push)
IP XX	Ingress protection degree provided by IEC 60529		Alternating current
	CE Marking		Medical Device
	LOT number		Date of Manufacture
	Serial number		Unique device identifier

General Notes:

- 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.
- This device (compressor, nebulizer kit, air tube, mouthpiece set, support adapter for child mask, adult and child mask) complies with the requirements of the European Standard EN ISO 27427:2019 Anaesthetic and respiratory equipment - Nebulizing systems and components.

- The nebulizer performance may vary with drugs such as suspensions or high viscosity solutions. See drug supplier's data sheet for further details.
- The particle size distribution and aerosol output may vary by combination of product, medication and ambient conditions such as temperature, humidity and atmospheric pressure.
- The disclosures for nebulizer performance are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric or infant populations.

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 kit.

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 40°C;
 - 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 retailer.

Repair or replacement under the guarantee 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

EN

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.l. 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
Subsidiaries	OMRON HEALTHCARE UK LTD. Opal Drive, Fox Milne, Milton Keynes, MK15 0DG, UK www.omron-healthcare.com/distributors
	OMRON MEDIZINTECHNIK HANDELSGESELLSCHAFT mbH / OMRON SANTÉ FRANCE SAS www.omron-healthcare.com/distributors

Made in Italy