

New Product Information Sheet

Specifications subject to change
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Model (code): C28P (NE-C105-E)



Versions	Remark	Date
1	w/o key visual and DoC information	12/10/2020
2	With full content	

Make every treatment truly efficient

New C28P prevents medication waste by precisely delivering the optimal dose, so you can be confident in an effective treatment, whether it's for you or someone in your family.

C28P

Highly-efficient nebulizer with A.V.T.



Built for intensive use with accessories that cover all ages

Advanced Valve Technology (A.V.T.) prevents medication from escaping when breathing in & out

Designed to be easy to use, clean, and store

C28P

Highly efficient Nebulizer for frequent use.

Product Name: C28P (NE-C105-E)

Product Description: Compressor Nebulizer

Product Category: Aerosoltherapy Equipment


Features

- Provides efficient medication deposition in the lungs to treat conditions such as bronchitis, bronchiolitis or asthma
- Advanced Valve Technology maximizes the amount of medication during inhalation and reduces medication loss during exhalation by synchronizing the flow
- MMAD 2,65 µm, Medication tank 2-12 ml

Packaging content

- Compressor
- Nebulizer Kit
- Adult Mask (PP+TPE)
- Child Mask (PP+TPE)
- Air Tube (PVC, 100 cm)
- Mouthpiece Set
- Adapter
- Carrying Bag
- 5 pcs Spare Air Filters
- Instruction Manual

Logistic information

Package	Amount	Approximate weight	Approximate dimensions (w) x (d) x (h)
Main Unit (compressor only)	1	1.3 kg	180 mm x 180 mm x 104 mm
Single Package	1	1.9 kg	193 mm x 265 mm x 143 mm
Master Carton	4	8.2 kg	278 mm x 173 mm x 790 mm
UDI-ID (Unique Device Identifier) / EAN code	 4 015672 112766		

Technical data

Product description:	Compressor Nebulizer
Product Category:	Aerosoltherapy Equipment
Model (code):	C28P (NE-C105-E)
Rating:	230V ~50Hz
Power Consumption:	140VA
Operating Mode:	Continuous use
Operating conditions:	+5°C to +40°C / 15% to 85%RH / 700 to 1060 hPa
Storage / Transport conditions:	-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 (PVC,150 cm), Mouthpiece, Adapter, Adult Mask, Child Mask, Carrying Bag, 5 pcs Spare Air Filters, Instruction Manual
Appropriate Medication Qty:	2 ml minimum - 10 ml maximum
Residual volume of Medication:	Approx. 0.7 ml
Sound: Noise level (at 1 m distance):	Approx. 55 dB
Particle Size (MMAD):	Approx. 2.65 µm
Aerosol Output (2 ml, 1% NaF):	Approx. 0.7 ml
Aerosol Output Rate (2 ml, 1% NaF):	Approx. 0.12 ml/min

General description

OMRON is introducing the C28P, a new addition to its Compressor Nebulizer portfolio. This product was developed in conjunction with respiratory therapists for the successful treatment of respiratory disorders such as asthma, chronic bronchitis, allergies, etc.

This is a medical device. Operate the device only as instructed by your doctor and/or respiratory therapist.

Packaging content

The manufacturer produces C28P with the applicable accessories included, necessary for meeting its intended purpose.

1. Compressor and power cable with EU plug
2. Nebulizer Kit
3. Child Mask (PP+TPE)
4. Adult Mask (PP+TPE)
5. Mouthpiece
6. Adapter
7. Air Tube (PVC, 150cm)
8. 5 pcs Spare Air Filters
9. Carrying Bag
10. Instruction Manual

The complete set of the medical device is specified in the Instruction Manual in the "Know your unit" section.

Purpose

The nebulizer is a medical device that is intended to be used for inhaling medication to treat respiratory disorders.

Application field

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

Intended User

- Persons who suffer from respiratory disorders and require inhalation of medications.
- Legally certified medical experts, such as doctor, nurse and therapist or healthcare personnel or patient under the guidance of qualified medical experts.

Before using this device please refer to "Important Safety Instructions" section of the Instruction Manual.

Indications for use

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

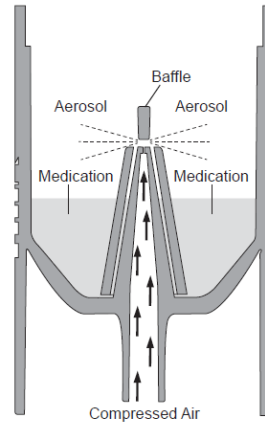
Features (Particularities)

- Provides efficient medication deposition in the lungs to treat conditions such as bronchitis, bronchiolitis, COPD or asthma
- Advanced Valve Technology maximizes the amount of medication during inhalation and reduces medication loss during exhalation by synchronizing the flow
- MMAD 2,65 μm , Medication tank 2-12 ml
- Suitable for the whole family
- Long-life compressor

Description of operating principle

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.



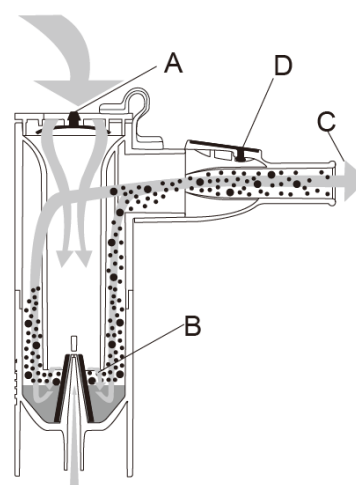
Nebulizer Kit with Valve Technology

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!

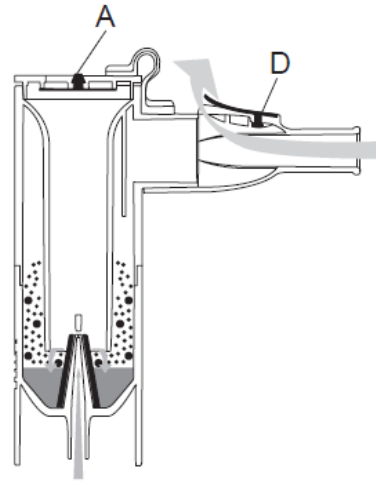
Inhalation phase:

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.



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).



How to use the device

Follow IM for detailed instructions!

Main steps:

1. Make sure that the power button is in the off position.
2. Insert the power cord into the compressor socket and then plug the power plug into a power outlet.
3. Remove the inhalation top from the medication tank.
4. Verify that the vaporiser head is attached to the inhalation top.
5. Add the correct amount of prescribed medication into the medication tank.
6. Put the inhalation top back onto the medication tank

Using the mouthpiece:

- 7a. Assemble the mouthpiece.
- 7b. Attach the mouthpiece to the nebulizer kit and press the cap onto the inhalation top.
- 7c. Keep the mouthpiece in the mouth during both inhalation and exhalation in order to get the maximal benefit by the valve system.

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.
8. Attach the air tube.
9. Hold the nebulizer kit straight. Do not tilt more than 30 degrees in all directions. Follow the instructions of your doctor or respiratory therapist.
10. Press the power button to power the compressor. 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.

Optional medical accessories

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

Other optional/replacement parts

<i>Product Description</i>	<i>Model</i>
Power Cord with EU plug	3AC459
Power Cord with EU plug	3AC460
Air Filter Set (Contents: 5 pieces)	3AC458

Materials used in main device

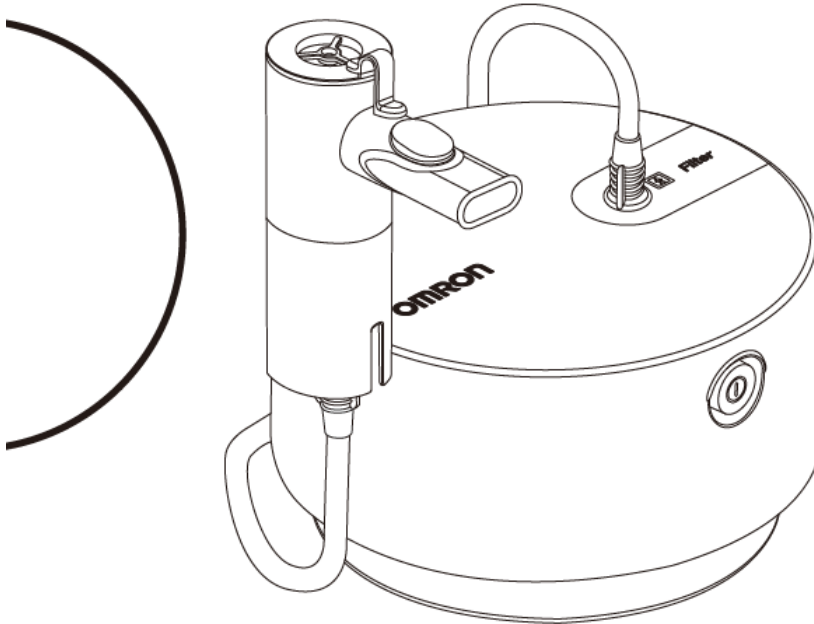
Part's name	Material	Grade	Colorant	Colorant grade
Housing and air filter cover	ABS (acrylonitrile butadiene styrene)	ESTADIENE 1640	White	WT-001
Air Filter	PP (polypropylene)	Geotess 350	White	RAL 9010
Legs	EPDM (Ethylene-Propylene Diene Monomer)	50 Shore A	Grey	RAL 7035
AC Power cord	PVC (polyvinyl chloride)	UL 94V-0	White	RAL 9010
Rating label	PET (polyester)	RI-COTE 36 AP900	Grey	Pantone 877C
Package	Cardboard	280g/m ² + TT44/E	White	RAL 9010
Instruction Manual	Paper	70g/m ²	White	RAL 9010
Warranty card	Paper	70g/m ²	White	RAL 9010
Carrying Bag	600D Oxford Cloth	AAA high quality	113 high temp. S-3BG220%, 121 low temp. E-RGFL100%, 133 high temp. S-5BL100%,514 Glacial acid	3.5

Materials for accessories

Item/part's name	Material	Grade	Colorant	Colorant grade
Medication Tank and Support Adapter for Child Mask	PP (polypropylene)	HP500N	Transparent	No additional colorant
Inhalation Top of the Neb kit	PP (polypropylene)	HP500N	White	WT-001
Mouthpiece with Cap	PP (polypropylene) and	HP500N	White	WT-001
	TPE (Thermoplastic elastomers)	TM7MED	Light Grey	GY-003
Inhalation and Exhalation valves	Silicone	PT SA 60	Light Grey	GY-003
Vaporiser Head	PP (polypropylene)	HP500N	Transparent Blue	Pantone T225-1-2
Adult Mask and Child Mask	PP (polypropylene) and	HP500N	Transparent	No additional colorant
	TPE (Thermoplastic elastomers)	TM5LFT	Light Grey	GY-003
Air Tube	PVC (polyvinyl chloride) – phthalate free	H4880TF AM276/D	Transparent light blue	Pantone 279C
Elastic band	PET (Polyester), Spandex	1680	Blue	Pantone 288C
Bag for accessories	PE (polyethylene)	50 microns	Transparent	No additional colorant in it

Title page of Instruction Manual

OMRON



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

EN

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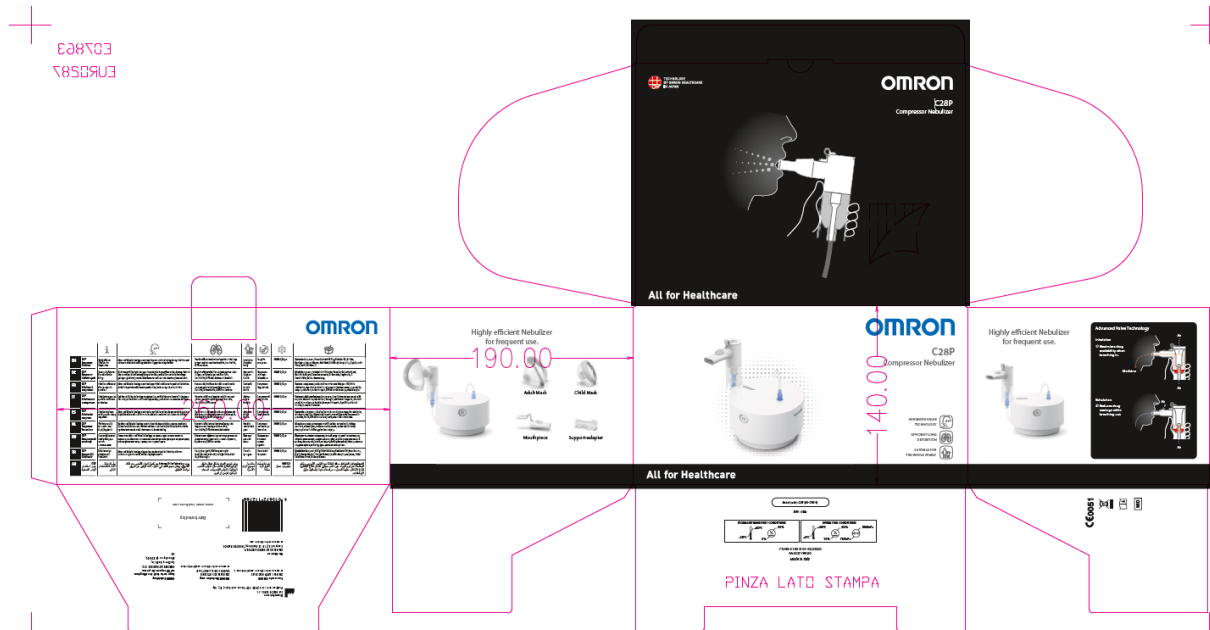
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All for Healthcare

Unfolded package design of main device and accessories

Main device:



Accessories: Nasal Shower NEB6014



List of Harmonized EN Standards

The device is classified as a medical device, class IIa.

Applicable standards:

EN 13544-1:2007+A1 :2009

EN ISO 15223-1:2016

EN 1041:2008+A1 :2013

UNI EN ISO10993-1:2010

EN 10993-5 :2009

EN 10993-10:2010

EN 60601-1:2006/A11 :2011/A1 :2013

EN 60601-1-2:2015

EN 60601-1-11:2015

EN 60601-1-6:2010+A1:2015

EN 62366-1:2015

EN ISO 14971:2012

Cleaning of the device

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)
- 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 cycles

● **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 disinfected 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.

● **Replacing the Air Filter:**

If the air filter has changed colour, 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.

Maintenance

This device does not require any regular maintenance.

Storage

Storage and transportation:

Temperature range: -20°C to +60°C

Humidity range: 5% to 95%RH

Atmospheric pressure: 500 - 1060hPa

Warnings

(Warning indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury.)

It is important that you read all the warnings and precautions included in this instruction manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the unit!

- 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.
- 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.

Disposal

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

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.

Transportation and storage conditions

Storage and transportation conditions:

1. Temperature range: -20 to +60°C
2. Humidity range: 5 to 95% RH

Warranty and lifetime

The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

Warranty of the compressor (main unit): 3 years.

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)..

Compressor (Main unit): 7,5 years

Power Cord: 7,5 years

Nebulizer Kit / Mouthpiece / Child Mask / Adult Mask / Adapter / Air Tube: 1 year;

Air Filter: 60 days

Durable period may vary depending on usage environment.

Frequent usage of the product may shorten the durable period.

Repair

Do not attempt to repair the device. Do not open and/or tamper with the device.

During the period of warranty OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts. Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.

Servicing

No parts of the device are user serviceable. Return it to an authorized OMRON retail outlet or distributor in case of any problem listed in Troubleshooting chapter of the Instruction Manual.

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.

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& PRODUCTION
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