

**General Information:**

Sales Name	NE-C28P
Item number	NE-C28P-E
Model Category	Compressor Nebulizer
Legal Manufacturer	<b>OMRON Healthcare Co., Ltd.</b> 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan
Production Facilities	<b>OMRON DALIAN Co., Ltd.</b> Economic and Technical Development Zone No.3 Song Jiang Road, Dalian 116600, China
Photo of Product	
Packaging Content	Compressor, Nebulizer Kit, Air Tube (PVC, 200cm), 5pcs Spare Air Filters, Mouthpiece, Adult Mask (PVC), Child Mask (PVC), Nosepiece, Storage Bag, Instruction Manual, Warranty Card,
EAN Code	4015672106369

## List of Harmonized EN Standards

### Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC

### Standards:

EN 60601-1:1990+A1:1993+A2:1995  
EN 60601-1-2: 2007  
EN 60601-1-6: 2007  
EN 980: 2008  
EN 1041: 2008  
EN ISO 14971: 2009  
EN 62366: 2008  
EN ISO 10993-1: 2009  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2009  
EN 13544-1: 2007 + A1:2009

### Place/Date:

Kyoto, Japan / January 5, 2012

## Intended Use

### Medical Purpose

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

### Intended User

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

### Intended Patients

This product should not be used by patients, who are unconscious or are not breathing spontaneously.

### Environment

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

## Particularities

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- A) **Powerful Compressor unit with a new high efficient nebulizer kit which includes our unique V.V.T. Technology. The nebulization rate of 0.5 ml/min ensures a fast and convenient treatment of asthma, chronic bronchitis, allergies and other respiratory disorders.**

The C28P is an upgrade successor of our current model C28. For the **C28P** we are using a new nebulizer kit, the same as for the C801, which **increases the performance** in regards to the nebulization rate. The high nebulization rate of 0.5 ml/min ensures to the patients **short inhalation times** and **efficient lung deposition**.

Easy **one-button operation** and **wide medication compliance** are further attributes of this long-life desktop compressor for a fast and convenient inhalation.

The C28P will replace the current C28.

- V.V.T. Nebulizer kit
- Adult and child mask
- High nebulization rate 0.5 ml/min
- Wide medication compliance
- Efficient lung deposition
- Handy carrying case
- Short nebulization times
- Simple one-button operation
- Hygienic – easy to clean
- Convenient nebulizer kit holder
- Long-life compressor


## Package Design



















## Packaging Information:

	Dimensions	Qty	Weight
Main Unit	170 x 182 x 103 mm	-	1.87kg
Package	250 x 190 x 144 mm	1	2.51kg
Master Carton	783 x 264 x 176 mm	4	11.5kg

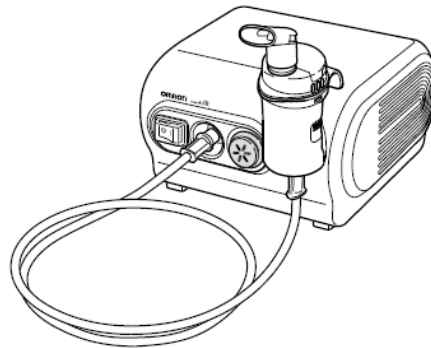
## Standard Content:

Contents of the sales package is marked with .  
All the items showed below can be purchased separately with the according order number.

<p><b>Omron V.V.T. Nebulizer Kit N-01 Set</b> Model: C801S-NSET3-E Order No.: 9515573-6</p>  <p>Mouthpiece</p>  <p>Nebulizer Kit No. : N-01</p> 	<p><b>Air Tube (PVC, 200cm)</b> Model: NEB-TP-L20E Order No.: 9520606-3</p>  	<p><b>Mouthpiece</b> Model: C28-3P-E Order No.: 9956273-5</p>  
<p><b>Adult Mask (PVC)</b> Model: C28-8-E Order No.: 9956275-1</p>  	<p><b>Child Mask (PVC)</b> Model: C28-9-E Order No.: 9956276-0</p>  	<p><b>Adult Mask (SEBS)</b> Model: U10-1P-E Order No.: 9956312-0</p>  <p>with elastic band</p>
<p><b>Child Mask (SEBS) Set</b> Model: U10-2P-E Order No.: 9956281-6</p>  <p>Child Mask (SEBS) with elastic band</p>  <p>Adapter for Child Mask (SEBS)</p>	<p><b>Air Filters (x 5)</b> Model: C28-2-E Order No.: 9956271-9</p>  	

## Instruction Manual Design

OMRON



COMP *A-I-R.*  
**Compressor Nebulizer**  
**Model NE-C28P**

- Instruction Manual
- Mode d'emploi
- Gebrauchsanweisung
- Manuale di istruzioni
- Manual de instrucciones
- Gebruiksaanwijzing
- РУКОВОДСТВО ПО ЭКСПЛУАТАЦИИ

• كتيب الإرشادات • AR

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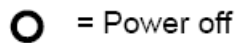
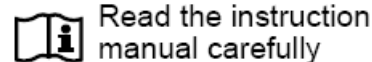
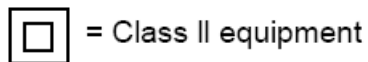
IM-NE-C28P-E-01-09/2011  
5334069-0A

Instruction Manual in Languages: EN, FR, DE, IT, ES, NL, RU, AR

## Technical Specifications

### 9. Technical data

<b>Product Description:</b>	Compressor Nebulizer
<b>Model:</b>	NE-C28P (NE-C28P-E)
<b>Electrical:</b>	220 - 240V, 50/60 Hz
<b>Power Consumption:</b>	192VA
<b>Operating Temperature/ Humidity:</b>	+10°C to +40°C 30% to 85% RH
<b>Storage Temperature/ Humidity/Air Pressure:</b>	-20°C to +60°C 10% to 95% RH 700 - 1060 hPa
<b>Weight:</b>	Approx. 1.9kg (compressor only)
<b>Dimensions:</b>	Approx. 170 (W) × 103 (H) × 182 (D) mm
<b>Contents:</b>	Compressor, Nebulizer Kit, Air Tube (PVC, 200cm), 5 pcs Spare Air Filters, Mouthpiece, Adult Mask (PVC), Child Mask (PVC), Nosepiece, Carrying Bag, Instruction Manual, Warranty Card.
<b>Classification:</b>	Class II equipment, Type B applied part



#### Notes:

- Subject to technical modification without prior notice.
- This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co., Ltd., Japan.
- The device may not work if the temperature and voltage conditions are different to those defined in the specifications.
- Do not use the device where it may be exposed to flammable gas.
- This device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN13544-1:2007+A1:2009, Respiratory therapy equipment - Part1: Nebulizing systems and their components.

**Particle Size:** \*\*MMAD Approx. 3µm

MMAD = Mass Median Aerodynamic Diameter

**Medication Tank Capacity:** 7ml maximum

**Appropriate Medication Quantities:** 2ml minimum – 7ml maximum

**Sound:** \*Approx. 60dB

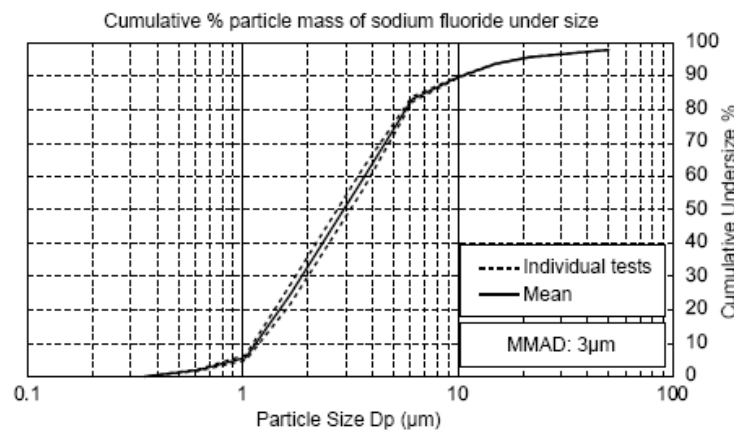
**Nebulization Rate:** \*Approx. 0.5ml/min (by weight loss)



**Technical data for the OMRON NE-C28P Compressor with the OMRON V.V.T. (Virtual Valve Technology) Nebulizer kit N-01:**

<b>Particle Size:</b>	*MMAD **approximately 3 $\mu$ m
<b>Medication Tank Capacity:</b>	7 ml maximum
<b>Appropriate Medication Quantities:</b>	2 ml minimum - 7 ml maximum
<b>Sound:</b>	Noise level (at 1 m distance) 60 dB
<b>Nebulization Rate:</b>	0.5 ml/min (by weight loss)
<b>Aerosol Output:</b>	**0.4 ml (2ml, 1%NaF)
<b>Aerosol Output Rate:</b>	**0.09 ml/min (2ml, 1%NaF)

**Result of cascade impactor measurements for particle size\*\***



\*MMAD = Mass Median Aerodynamic Diameter


\*\*Independently measured by Prof. Dr. Hiroshi Takano, Department of Chemical Engineering and Materials Science, Faculty of Science and Engineering, Doshisha University, Kyoto, Japan, according to EN13544-1:2007+A1:2009

**Notes:**

- Performance may vary with drugs such as suspensions or high viscosity. See drug supplier's data sheet for further details.
- See website of OMRON HEALTHCARE EUROPE to update technical information.

URL: [www.omron-healthcare.com](http://www.omron-healthcare.com)

### Comparative Table

Sales Name	NE-C28 (Predecessor)	NE-C28P	Note
Item Number	NE-C28-E	NE-C28P-E	
Rating (AC adapter)	220-240V, 50/60Hz	220-240V, 50/60Hz	Same
Power Consumption	192VA	192VA	Same
Dimensions (W x H x D: mm)	170 x 103 x 182	170 x 103 x 182	Same
Weight	1.9kg (compressor only)	1.9kg (compressor only)	Same
Nebulization Rate	Approx. 0.4ml/min (by weight loss)	Approx. 0.5ml/min (by weight loss)	Higher
Particle Size	MMAD approx. 3µm	MMAD approx. 3µm	Same
Medication Tank Capacity	7ml maximum	7ml maximum	Same
Compressor	AC motor pump	AC motor pump	Same
Child Mask	Yes	Yes	Same
Adult Mask	Yes	Yes	Same
Mouthpiece	Yes	Yes	Same
Storage Bag	Yes	Yes	Same
Air Filter	5 pcs	5 pcs	Same
Air Tube	Yes	Yes	Same
Nosepiece	Yes	Yes	Same
			

#### Conclusion of Comparison NE-C28 versus NE-C28P

The **new model** NE-C28P is a substantial equivalent of its predecessor NE-C28 in terms of Technology, functionality, Used materials, Safety, Reliability, Performance and Clinical application.

### List of Materials

Item	Material	Grade
Top Housing	Acrylonitrile butadiene styrene	GP-22 or 100-MPJ
Housing Bottom	Acrylonitrile butadiene styrene	GP-22 or 100-MPJ
Housing Front	Acrylonitrile butadiene styrene	GP-22
Housing Side	Acrylonitrile butadiene styrene	GP-22 or 100-MPJ
Cap Filter	Acrylonitrile butadiene styrene	BUA2022A
Switch Cover	Polyvinyl Chloride (Phthalate free)	FJ-110
Medication Tank of Nebulizer-kit	Polypropylene	J246MA
Inhalation Top of Nebulizer-kit	Polypropylene	NOVATEC BC03B
Cap of Nebulizer-kit	Polypropylene	NOVATEC BC03B
Vaporiser Head	Polycarbonate	Panlite L1225T
Air Tube	Polyvinyl Chloride (Phthalate free)	NP-3072 75A15B
Mouthpiece	Polypropylene	NOVATEC BC03B
Nosepiece	Polypropylene	MH04
Mask	Polyvinyl Chloride (Phthalate free)	NP-3072 75A15B
Mask Band	Spandex	AS201/8

## Maintenance and Storage

To keep your device in the best condition and protect the device from damage follow these directions:

### Caution:

- Do not leave the device unattended with infants or persons who cannot express their consent.
- Do not subject the device or the parts to any strong shocks such as dropping the device on the floor.
- Do not carry or leave the nebulizer kit while the medication tank contains medication.

### Notes:

- Do not store the device in extreme hot or cold temperatures, high humidity or under direct sunlight.
- Do not crease or fold the air tube.
- Dispose of the device and any used accessories or optional parts according to applicable local regulations.
- Never clean with benzene, thinner or a flammable chemical.
- Always transport the device in its storage bag, and store the device in the bag if it will not be used for a long period.

## Lifetime

The durable period for the main unit is 5 years; 3 times a day for 10 minutes each time at room temperature (23°C).

Nebulizer kit and optional parts: 1 year

## **Warranty card text as included in the product**

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 covers only products purchased in Europe, Russia and other CIS countries, Middle East and Africa.**

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 unauthorised persons.
- c. Periodic check-ups and maintenance.
- d. Failure or wear of accessories 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.