

General Information:

Sales Name	NE-C900
Item number	NE-C900-E
Model Category	Compressor Nebulizer
Legal	OMRON Healthcare Co., Ltd.
Manufacturer	53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan
Production Facilities	OMRON DALIAN Co., Ltd. Economic and Technical Development Zone No.3 Song Jiang Road, Dalian 116600, China
Photo of	
Product	Omeon Control of the
Packaging	Compressor, Nebulizer Kit, Air Tube (PVC, 200cm), 5pcs Spare Air
Content	Filters, Mouthpiece, Adult Mask (PVC), Child Mask (PVC),
	Nosepiece, Instruction Manual, Warranty Card,
EAN Code	4015672106499



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 / April 16, 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-C900 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



High-performance Compressor unit with a new high efficient nebulizer kit called S.S.K (Smart Structure Kit). The new designed nebulizer kit contains just two parts for an easy preparation and cleaning. The high-output of 7L (Airflow L/min) at 100 kPa (pressure) fulfills the requirement for a successful Hospital business. The nebulization rate of 0.4 ml/min ensures a fast and convenient treatment of asthma, chronic bronchitis, allergies and other respiratory disorders.

3µm MMAD ensures an efficient lung deposition at the lower airways.

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

The C900 will replace in medium term the current C29.

- High-output compressor
- 7L at 100kPa
- Two part S.S.K (Smart Structure Kit) for easy preparation and cleaning
- High nebulization rate 0.4 ml/min
- Wide medication compliance
- Efficient lung deposition at lower airways
- Convenient handle for carrying safely
- Short nebulization times
- Simple one-button operation



Package Design



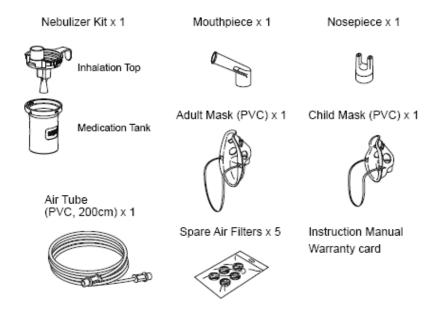
Packaging Information:

	Dimensions WxDxH	Qty	Weight
Main Unit	175 x 215 x 110 mm	-	2.2kg
Package	272 x 198 x 195 mm	1	3.5kg
Master Carton	576 x 422 x 240 mm	4	12.8kg



Standard Content:

All the items showed below can be purchased separately with the according order number.



Accessories

Name	Model	Order No.
Nebulizer Kit & Mouthpiece Set	NEB-NSET3-90E	9520555-5
Adult Mask (PVC)	C28-8-E	9956275-1
Child Mask (PVC)	C28-9-E	9956276-0
Infant Mask (PVC)	NEB-MSSP-E	9520250-5
Adult Mask (SEBS)	U10-1P-E	9956312-0
Child Mask (SEBS) Set	U10-2P-E	9956281-6
Mouthpiece	C28-3P-E	9956273-5
Nosepiece	C28-7-E	9956274-3
Air Tube (PVC, 200cm)	NEB-TP-L20E	9520606-3
Air Filters x 5	C28-2-E	9956271-9



Instruction Manual Design



Compressor Nebulizer
Model NE-C900

Instruction Manual

All for Healthcare

IM-NE-C900-E-EN-01-02/2012 1675345-3A

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



Technical Specifications

Technical data

Name: COMP AIR Pro

 Model:
 NE-C900 (NE-C900-E)

 Type:
 Compressor Nebulizer

 Rating:
 AC 220-240V, 50Hz

Power Consumption: 220VA

Operating Temperature/

Storage and Transport

Humidity:

+10°C to +40°C / 30% to 85%RH

-20°C to +60°C / 10% to 95%RH / 700 - 1060hPa

Temperature/Humidity/ Air Pressure:

Weight: Approx. 2.2kg (compressor only)

Dimensions: Approx. 175 (W) × 110 (H) ×215 (D) mm

(compressor only)

Contents: Compressor, Nebulizer Kit, Air Tube (PVC,

200cm), Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), 5 pcs Spare Air Filters, Instruction Manual, Warranty Card.

Classification: Class II equipment, Type B applied part

= Class II equipment

iss II 🗼 = Type B uipment applied part Read the instruction manual carefully

O = Power off $I = Power on C \in 0.197$



Technical data for the OMRON NE-C900 Compressor with the Nebulizer Kit:

Particle Size: **MMAD Approx. 3µm

MMAD = Mass Median Aerodynamic Diameter

Medication Tank Capacity: 7ml maximum

Appropriate Medication

Quantities:

2ml minimum - 7ml maximum

Sound: *Approx. 55dB

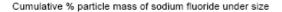
Nebulization Rate: *Approx. 0.4ml/min (by weight loss)

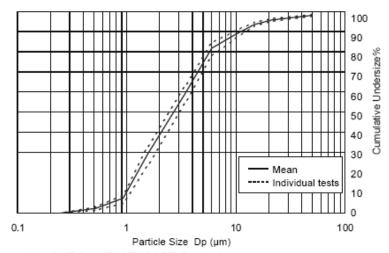
Airflow/Compressor *7L/min @100kPa

Output:

Aerosol Output: **0.57ml (2ml, 1%NaF)
Aerosol Output Rate: **0.08ml/min (2ml, 1%NaF)

Result of cascade impactor measurements for particle size**





- Measured by OMRON HEALTHCARE Co., Ltd.
- ** 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 EN 13544-1:2007+A1:2009.

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.
- 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.
- 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



Comparative Table

Sales Name	NE-C29 (Predecessor)	NE-C900	Note
Item Number	NE-C28-E	NE-C900-E	
Rating (AC adapter)	220-240V, 50/60Hz	220-240V, 50Hz	Different
Power Consumption	192VA	220VA	Higher
Dimensions (W x H x D: mm)	170 x 103 x 182	175 x 110 x 215	Different
Weight	1.9kg (compressor only)	2.2kg (compressor only)	Higher
Nebulization Rate	Approx. 0.4ml/min (by weight loss)	Approx. 0.4ml/min (by weight loss)	Same
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	No	Different
Air Filter	5 pcs	5 pcs	Same
Air Tube	Yes	Yes	Same
Nosepiece	Yes	Yes	Same

Conclusion of Comparison NE-C29 versus NE-C900

The new model NE-C900 is a substantial equivalent of its predecessor NE-C29 in terms of Technology, functionality, Used materials, Safety, Reliability, Performance and Clinical application.



List of Materials

Parts Name	Material	Grade
HOUSING BOTTOM	acrylonitrile butadiene styrene	GP22
HOUSING TOP	acrylonitrile butadiene styrene	GP22
CPA FILTER	acrylonitrile butadiene styrene	EX-120— BUA2022A
FRONT HOUSING	acrylonitrile butadiene styrene	100MPJ
MASK PVC NF(L)	polyvinyl chloride (phthalate free)	NP-3072 75A15B
MASK PVC NF(M)	polyvinyl chloride (phthalate free)	NP-3072 75A15B
NOSE PIECE	polypropylene	MH04
MOUTHPIECE	polypropylene	novatec BC03B
TUBE PVC NF	polyvinyl chloride (phthalate free)	NP-3072 75A15B
INHALATON TOP	polypropylene	M800E
MEDICATION TANK	polypropylene	M800E



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; 2ml of medication 10 times a day for 6 minutes each time at room temperature $(23^{\circ}C)$.

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.