


General Information:

Sales Name	CompAir basic
Item number	NE-C802-E
Model Category	Compressor Nebulizer
Legal Manufacturer	OMRON Healthcare Co., Ltd. 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	
Packaging Content	Compressor, Nebulizer Kit, Air Tube (PVC, 100cm), 5pcs Spare Air Filters, Mouthpiece, Adult Mask (PVC), Child Mask (PVC), Nosepiece, AC Adapter, Storage Bag, Instruction Manual, Warranty Card,
EAN Code	4015672107090

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: Kyoto, Japan

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 CompAir basic 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



Smallest OMRON Compressor unit with an extremely compact size and easy to use. The nebulization rate of 0.25 ml/min ensures a convenient treatment of light asthma, chronic bronchitis, allergies and other respiratory disorders.

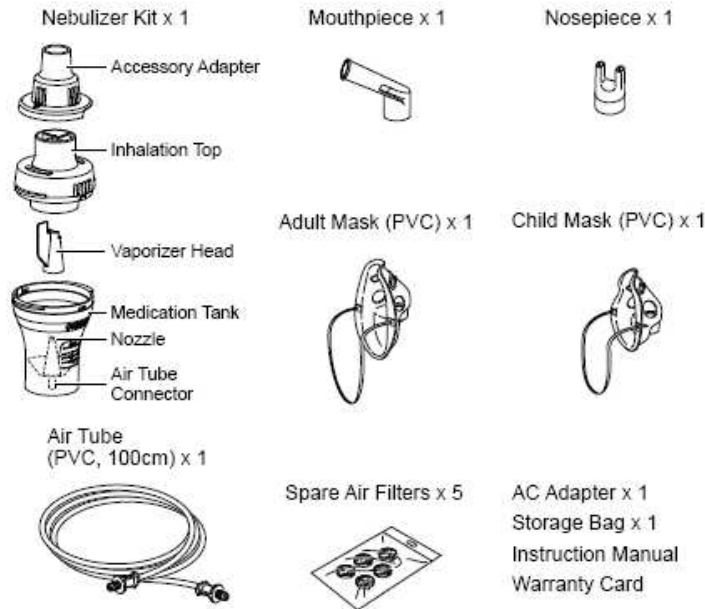
The **CompAir basic** features a new design with a very small footprint, which allows for convenient placing and storage of the device. Easy **one-button operation** and **low noise operation of less than 45 dB** are further attributes of this entry level compressor.

The **CompAir basic** is an amendment to the current OMRON compressor range portfolio.

- MMAD approx. 3 μ m
- Nebulization rate 0.25 ml/min
- Compact size
- Low noise compressor (45dB)
- Efficient lung deposition
- Adult and child mask
- Handy carrying case
- Simple one-button operation
- Hygienic – easy to clean
- Convenient nebulizer kit holder

Standard Content:

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



Optional Medical Accessories

(within the scope of EC Medical Device Directive 93/42/EEC)

Name	Model	Order No.
Nebulizer Kit & Mouthpiece Set	NEB-NSET3-82E	9065690-7
Adult Mask (PVC)	NEB-MSLP-E	9956275-1
Child Mask (PVC)	NEB-MSMP-E	9956276-0
Adult Mask (SEBS)	NEB-MSLS-E	9956312-0
Child Mask (SEBS) Set	NEB-MSSS-E	9956281-6
Mouthpiece	NEB-MP-E	9956273-5
Nosepiece	NEB-NP-E	9956274-3
Air Tube (PVC, 100cm)	NEB-TP-82E	9065693-1
AC Adapter	NEB-AC-82E	9065656-7

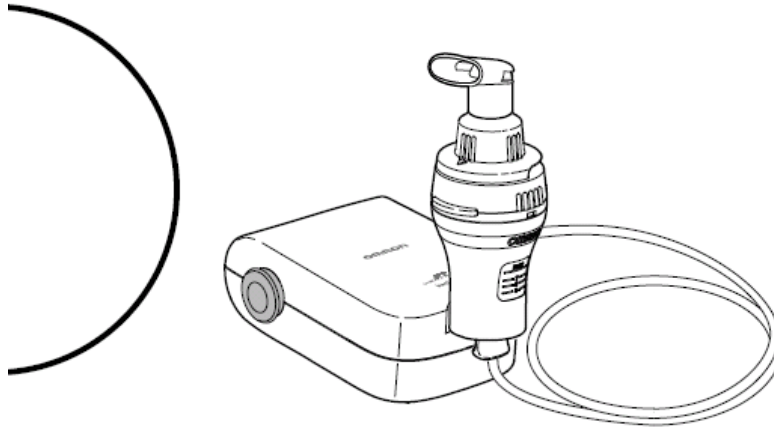
and

Other Optional/Replacement Parts

Name	Model	Order No.
Air Filters x 5	NEB-AFR-30E	9956636-6

Instruction Manual Design

OMRON



COMP *A-I-R* basic

EN

Compressor Nebulizer

Instruction Manual

All for Healthcare

IM-NE-C802-E-EN-01-04/2012
1675453-0A

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

Technical Specifications

Technical data

Name:	COMP AIR basic
Model:	NE-C802 (NE-C802-E)
Type:	Compressor Nebulizer
Rating (AC adapter):	100-240V ~ 50/60Hz 15VA
Rating (Compressor Nebulizer):	6V = 0.6A
Operating Temperature/ Humidity:	+10°C to +40°C / 30% to 85%RH
Storage and Transport Temperature/Humidity/ Air Pressure:	-20°C to +60°C / 10% to 95%RH / 700 - 1060hPa
Weight:	Approx. 190g (compressor only)
Dimensions:	Approx. 85 (W) × 43 (H) × 115 (D) mm (compressor only)
Contents:	Compressor, Nebulizer Kit, Air Tube (PVC, 100cm), Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), 5 pcs Spare Air Filters, AC Adapter, Storage Bag, Instruction Manual, Warranty Card.
Classification:	Class II equipment, Type BF applied part



= Class II
equipment



= Type BF
applied part



Read the instruction
manual carefully



= No operation



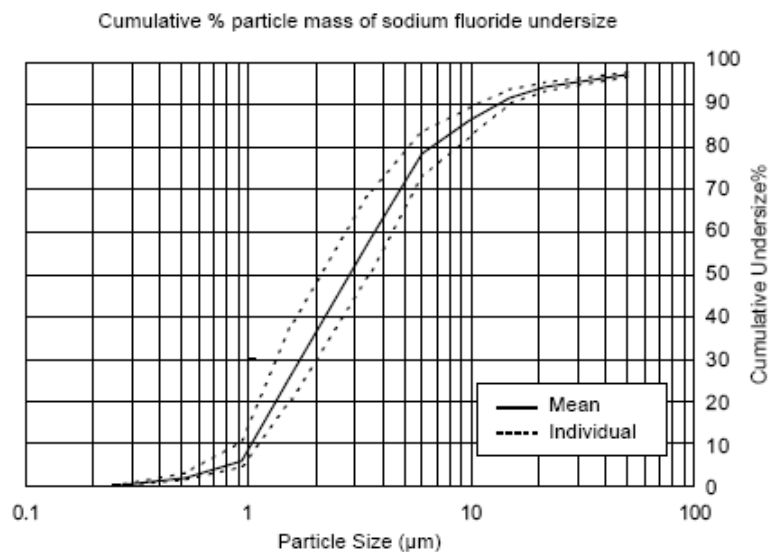
= Power on

CE 0197

Technical data for the OMRON NE-C802 Compressor with the Nebulizer kit:

Particle Size:	**MMAD Approx. 3 μ m MMAD = Mass Median Aerodynamic Diameter
Medication Tank Capacity:	10ml maximum
Appropriate Medication Quantities:	2ml minimum - 10ml maximum
Sound:	*Less than 45dB
Nebulization Rate:	*Approx. 0.25ml/min (by weight loss)
Aerosol Output:	**0.56ml (2ml, 1%NaF)
Aerosol Output Rate:	**0.07ml/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.
- The 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-C801 (Predecessor)	CompAir basic	Note
Item Number	NE-C801S-E	NE-C802-E	
Rating (AC adapter)	100-240V, 50/60Hz	100-240V, 50/60Hz	Same
Weight	270g (compressor only)	190g (compressor only)	Different
Nebulization Rate	Approx. 0.3ml/min (by weight loss)	Approx. 0.25ml/min (by weight loss)	Different
Particle Size	MMAD approx. 3µm	MMAD approx. 3µm	Same
Medication Tank Capacity	7ml maximum	10ml maximum	Different
Compressor	DC pump	DC pump	Different
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-C801S-E versus NE-C802-E

The **new model** NE-C802-E is a substantial equivalent of its predecessor NE-C801S-E 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	GP22
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
ADAPTER	polypropylene	J246MA
VAPORIZER HEAD	polycarbonate	L-1225T
MEDICATION CUP	polypropylene	MA04A
INHALATION TOP	polypropylene	J246MA

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 twice a day for 8 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 unauthorized 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.