



## New Product Information Sheet

Specifications subject to change  
© OMRON HEALTHCARE EUROPE B.V.

Model (code):  
DuoBaby (NE-C301-E)

**Product description:** *Compressor Nebulizer with Nasal Aspirator*

**Product category:** *Nebulizers*

**Model (code):** *DuoBaby (NE-C301-E)*



#### **LEGAL MANUFACTURER & PRODUCTION FACILITY**

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

Phone: +31 23 5544700  
Fax: +31 23 5544701  
E-mail: [info.omronhealthcare@eu.omron.com](mailto:info.omronhealthcare@eu.omron.com)

## Included accessories / optional accessories

### Optional Medical Accessories

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

Product description	Model
DuoBaby Nebulizer accessory set (contents: nebulizer kit (includes two inhalation tops), baby mask, adult mask, mouthpiece, 3 air filters, air tube)	NEB2012
DuoBaby Aspirator accessory set, (contents: nasal aspirator, air tube)	NEB7000

### Other Optional/Replacement Parts

Product description	Model
Air Filter set (contents: 3 pieces)	3AC408

## General description

OMRON is introducing the DuoBaby NE-C301-E a Compressor Nebulizer with Nasal Aspirator.

This product was developed in conjunction with respiratory therapists for the successful treatment of asthma, chronic bronchitis, allergies, blocked nose, and other respiratory disorders. This is a medical device. Operate the device only as instructed by your doctor and/or respiratory therapist.

### Packaging content

The manufacturer produces the NE-C301-E with the applicable accessories included, necessary for the application of its intended purpose.

1. Compressor
2. Nebulizer Kit incl. 2 inhalation tops
3. Air tube
4. Mouthpiece
5. Baby Mask
6. Nasal Aspirator
7. Instruction Manual

## Purpose

The intended purpose of this product is:

- To allow for nebulization treatment of respiratory tract disorders.
- To remove mucus from the nasal cavities to ease breathing.

## Application field

This product is intended for use in a general household.

## Intended User

- Patient and/or caregiver under the direction of legally certified medical experts, such as doctor, nurse and therapist or qualified medical experts for home treatment.
- The user should also be capable of understanding general operation of DuoBaby and the content of this instruction manual.

## Indications for use

Medical product's intended use as determined by the manufacturer:

Intended Patients: Persons from the age of 1 month who suffer from upper airway conditions (such as blocked nose, cold, allergies) and/or lower respiratory conditions (such as asthma, bronchitis, bronchiolitis).

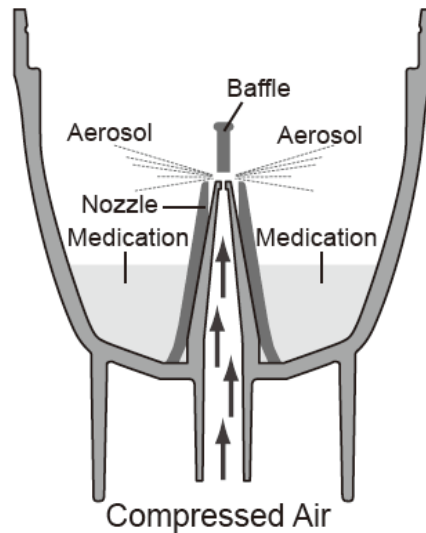
## Features (Particularities)

- 2 in 1 Compressor Nebulizer with Nasal Aspirator
- Nasal Aspirator gently clears the nose
- Efficient nebulization of upper and lower airways by means of two separate inhalation tops:
  - 1) Green inhalation top for Upper Airways – MMAD Approx. 9µm and nebulization rate of more than 0.4ml/min
  - 2) Blue inhalation top for Lower Airways - MMAD Approx. 4µm and nebulization rate of more than 0.2ml/min
- Accessories compartment with lid

## Description of operating principle

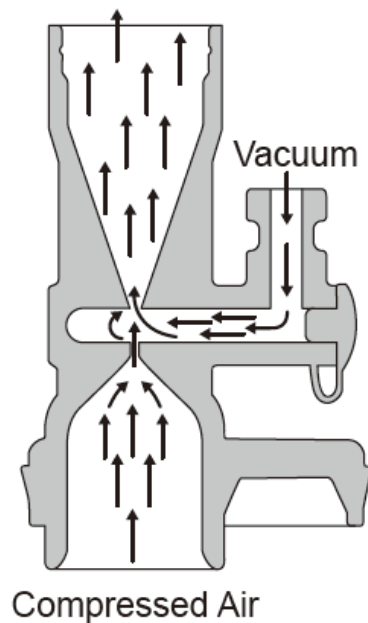
### How the nebulizer kit works

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.



### How the nasal aspirator kit works

The compressed air generated by the compressor pump, passing through a narrowing, thanks to the Venturi effect, creates a vacuum which sucks the mucus into the collection chamber.



## How to use nebulizer kit

1. Make sure that the power switch is in the off position.
2. Plug the power plug into a power outlet.
3. Remove the inhalation top from the medication tank.
  - Rotate the inhalation top anti-clockwise
  - Lift the inhalation top out from the medication tank.
4. Add the correct amount of prescribed medication into the medication tank.
5. Verify the presence of the vaporiser head inside the medication tank.
6. Choose the appropriate inhalation top by reading the “User Guidance”.  
To put the inhalation top back onto the medication tank.
  - Lower the inhalation top onto the medication tank.
  - Rotate the inhalation top clockwise.
7. Attach the Baby mask or mouthpiece to the nebulizer kit tightly.
8. Attach the air tube. While twisting the air tube plug slightly, push it firmly into the air tube connector.
9. Hold the nebulizer kit straight. Do not tilt more than than 60 degrees. Follow the instructions of your doctor or respiratory therapist.
10. Turn the power switch to the on position. As the compressor starts, nebulization begins and aerosol is generated. Inhale the medication. Exhale through the nebulizer kit.
11. When treatment is completed, turn the power off and unplug the compressor from the power outlet.
12. Clean and disinfect all (disassembled) parts.

## How to use Nasal Aspirator


Dry and very thick mucus inside the nose may be dissolved by saline solutions. After adding saline solution into each nostril of the baby’s nose to help loosen nasal secretions, wait a few minutes and then remove the mucus running out with a tissue. Only after removing the running mucus outside the nostrils the nasal aspirator may be used.

1. Make sure that the power switch is in the off position.
2. Assemble the nasal aspirator. Make sure that the O-ring is properly attached.
3. Plug the power plug into a power outlet.
4. Connect the air tube to the nasal aspirator and to the main unit, while twisting the air tube plugs slightly, push them firmly.
5. Keep your baby in a comfortable position and make sure that their head is lifted as shown on the figure to the right.
6. Turn the power switch to the on position. Place your index finger over the opening on the nasal aspirator, as shown on the figure to the right to begin aspiration.
7. Place the nozzle at the entrance of one of the nostrils of the baby (do not insert inside the nostril). Use the aspirator for 3 seconds for 4 times per nostril.

8. When treatment is completed, turn the power off and unplug the compressor from the power outlet.
9. Disconnect the aspirator from the air tube and disassemble it into 3 parts. Clean or disinfect.

Review the Instruction Manual for the full details on the application of this product.

### Technical data

Product Description:	Compressor Nebulizer with Nasal Aspirator
Model (code):	DuoBaby (NE-C301-E)
Rating	230 V – 50 Hz
Operating Temperature/Humidity/Air Pressure:	+10°C to +40°C / 10% to 95%RH / 690 – 1060hPa
Storage and Transport Temperature/Humidity/Air Pressure:	-20°C to +70°C / 5% to 95%RH / 690 - 1060hPa
Applied Part:	 = Type BF
Weight:	Approx. 1.7 kg (compressor only)
Outer Dimensions:	Approx. 170 (W) x 280 (D) x 105.5 (H) mm
Package Contents:	Compressor, Nebulizer Kit, Air tube, Mouthpiece, Baby Mask, Nasal Aspirator, Instruction Manual.
Classifications:	Class II equipment Type BF IP21
Particle size MMAD:	Upper Airways: Approx. 9µm Lower Airways: Approx. 4 µm *MMAD = Mass Median Aerodynamic Diameter
Appropriate Medication Quantities:	1 ml minimum - 12 ml maximum
Sound:	Noise level (at 1 m distance) 63 dB
Nebulization Rate (by weight loss):	Upper Airways: Approx. 0.4 ml/min Lower Airways: Approx. 0.2 ml/min
Aerosol Output (3 ml, 1% NaF):	Upper Airways: Approx. 0.54 ml Lower Airways: Approx. 0.50 ml
Aerosol Output Rate (1% NaF):	Upper Airways: Approx. 0.16 ml/min Lower Airways: Approx. 0.12 ml/min
Nasal Aspirator Suction Pressure:	Minimum -0.15 bar - Maximum -0.2 bar
Nasal Aspirator Air Flow:	Approx. 4 l/min
Nasal Aspirator Maximum fill volume of collection chamber:	7 ml

### Materials used in main device

Item	Material
Housing	ABS (acrylonitrile butadiene styrene)
Lid	PP (polypropylene)
Filter cover	ABS (acrylonitrile butadiene styrene)
Air Filter	PP (polypropylene)
Legs	EPDM (Ethylene-Propylene Diene Monomer)
Switch cover	PVC (polyvinyl chloride)
Switch	Nylon (Polyamide PA 66)
AC Cord	PVC (polyvinyl chloride)
Rating label	PET (polyester)
Bag for accessories	PE (polyethylene)
Package	Cardboard
Instruction Manual	Paper

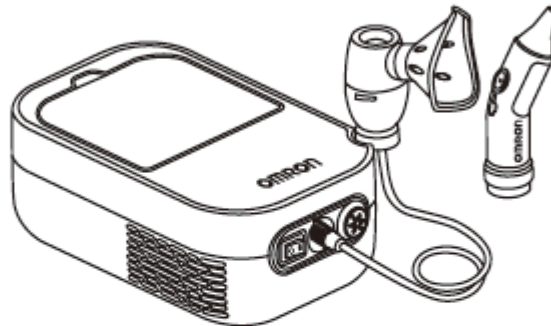
### Materials used in accessories

Item	Material
Nebulizer kit	PP (polypropylene)
Air Tube	PVC (polyvinyl chloride) – phthalate free
Nasal aspirator	PP (polypropylene)
O-rings of Nasal aspirator	Silicone
Mouthpiece	PP (polypropylene)
Baby Mask	PVC (polyvinyl chloride) – phthalate free
Adult Mask	PVC (polyvinyl chloride) – phthalate free



## Title page of Instruction Manual

OMRON



EN

### Compressor Nebulizer with Nasal Aspirator

DuoBaby (NE-C301-E)

### Instruction Manual

All for Healthcare

IM-NE-C301-E-EN-01-05/2016  
3A3427 rev.00

## Unfolded package design of main device and accessories

### Main device:



### Packaging specifications

Package	Amount	Approx. weight	Approx. dimensions W x D x H mm
Main Unit	1	1.7 kg	170 x 280 x 105 mm
Package	1	2 kg	290 x 113 x 177 mm
Master Carton	6	12.6 kg	359 x 312 x 376 mm

**Accessories:**

**Model: NEB7000**

**Product Description: DuoBaby Aspirator accessory set**



**Model: NEB2012**

**Product Description: DuoBaby Nebulizer accessory set**



## List of Harmonized EN Standards

The above mentioned medical device belongs to a IIa potential risk class.

Applicable Directives: Medical Device Directive (MDD) 93/42/EEC

Standards:

EN 13544-1:2009  
EN 15223-1:2012  
INI EN 1041:2013  
UNI EN ISO10993-1:2010  
EN 10993-5:2009  
EN 10993-10:2010  
EN 60 601-1:2006  
EN 60 601-1-2:2007 3a edition  
EN 60 601-1-11:2010  
EN 60 601-1-6:2010  
EN 62366:2008  
EN 14971:2012

## Operation and care

### Cleaning of the device

Clean the parts after each use to remove residual medication or mucus. This will prevent inefficient nebulization or aspiration and reduce the risk of infection. Do not use a brush or pin to clean.

• **Washable parts:** *Nebulizer kit, Baby Mask (PVC), Nasal Aspirator, Mouthpiece*  
Wash them 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 DuoBaby nebulizer kit or nasal aspirator after some 100 to 120 treatments or after about 20 boiling cycles.










• **Non-washable parts:** *Compressor, Air Tube (PVC)*

Firstly, 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. Air Filter Do not wash or clean the air filter.








### Disinfecting

Always disinfect the parts after the last treatment of the day. If the parts are heavily stained, replace them with new ones. To select a method for disinfection, refer to the table in instruction manual.

## Icons in the IM:

	Class II equipment
	Alternating current
	Type BF applied part
	Power on
	Power off
	Read the instruction manual carefully.
	This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive)
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment)
	Legal manufacturer

## Icons in the package:

	Legal manufacturer
	This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive)
	Read the instruction manual carefully
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment)
	Storage/Transport temperature
	Storage/Transport humidity
	Storage/Transport air pressure

## Warnings

Read all the information in the instruction manual and any other literature included in the box before using the device.

**Warning:** Indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

- A single-patient use is recommended.
- Do not use the device for other use than nebulization for human aerosol therapy and for removing the mucus.
- Manufacturer will not be held responsible for inappropriate use of the device.
- Use only original OMRON accessories as indicated in this instruction manual.
- The correct functioning of the device may be affected by electromagnetic interference caused by malfunctioning television sets, radios, etc. If this occurs, move the source of interference away from the device or use a different plug.
- For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist. Before use check that you are using the correct Inhalation top.
- If you feel or see anything unusual during use, stop using the device immediately and consult your doctor.
- Do not use only water in the nebulizer for inhaling purposes.
- Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- In view of their length, the power cord and air tube could constitute a strangulation hazard.
- Do not store the air tube while there is moisture remaining inside.
- Always dispose of any remaining medication after use, and use fresh medication each time.
- Do not use in anaesthetic or ventilator breathing circuits.
- Never block the ventilation slots. Never place the device where the ventilation slots may be obstructed during operation.
- Never leave the nebulizer kit with medication near the ventilation slots, this is to avoid medication entering the device.
- Store the parts in a clean location for avoiding infection.

### **(Risk of electrical shock)**

- Never plug or unplug the device with wet hands.
- The compressor and power cord are not waterproof. Do not spill water or other liquids on these parts. If liquid does spill on these parts, immediately unplug the power cord and wipe off the liquid.
- Do not immerse the compressor in water or other liquid.
- Do not use or store the device in humid locations.
- Do not operate the device with a damaged power cord or plug.
- Keep the power cord away from heated surfaces.
- Always unplug the device from the power outlet after use and before cleaning.



- Plug the device into the appropriate voltage outlet. Do not overload power outlets or use extension cords.
- Do not misuse the power cord.
- Do not wind the power cord around the compressor.

### **(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. For the instructions, refer to “Cleaning and daily disinfecting” section of the instruction manual.

- Clean and disinfect the nebulizer kit, baby mask, mouthpiece and nasal aspirator before using them when as follows:
  - the first time after purchase
  - if the device has not been used for a long period of time
  - if more than one person uses the same device
- Be sure to wash or wipe the parts after use, and ensure that they are thoroughly disinfected and dried, and stored in a clean location.
- Do not leave the cleaning solution in the parts.
- Do not use a microwave oven, dish dryer or hair dryer to dry the device or the parts.
- Do not use an autoclave, EOG gas sterilizer or low temperature plasma sterilizer.
- When disinfecting parts by boiling, make sure that the container does not boil dry. Otherwise it may also result in fire.

**Caution:** Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury, or physical damage.

## **Disposal**

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.

The main constituents of each part are listed in the table “Materials List”.

## **Transportation and storage conditions**

- Do not store the air tube while there is moisture remaining inside.
- Never leave the nebulizer kit with medication near the ventilation slots, this is to avoid medication entering the device.
- Store the parts in a clean location for avoiding infection.
- Do not use or store the device in humid locations.
- Do not use or store the device while the air tube is creased.

Storage and transportation:

Temperature range: -20°C to +70°C  
Humidity range: 5% to 95%RH  
Atmospheric pressure: 690 - 1060hPa

## **Warranty and lifetime**

Warranty of the nebulizer: 3 years.  
Lifetime of the nebulizer: 5 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). Durable period may vary depending on usage and environment.

Compressor (Main unit) - 5 years  
Nebulizer Kit - 1 year  
Mouthpiece - 1 year  
Air Tube - 1 year  
Air Filter - 70 applications  
Baby Mask - 1 year  
Nasal Aspirator - 1 year

## **Repair**

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

## **Servicing**

The device is not 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.