

New Product Information Sheet

Specifications subject to change
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Category, model and code of the product

Product Description: Compressor Nebulizer

Model (code): A3 Complete (NE-C300-E)

Legal Manufacturer and Production Facility

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Picture of the product



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SWIFT BOTKNL2X
CHAMBER OF COMMERCE NR. 342.10306
BTW/VAT NR. NL8132.86.281.B01

Packaging Contents

1. Nebulizer kit
2. Mouthpiece
3. Nosepiece
4. Adult Mask (PVC)
5. Child Mask (PVC)
6. Air Tube (PVC)
7. Spare Air Filters
8. Carrying bag
9. Instruction Manual

General description / purpose

Compressor nebulizer A3 Complete is a medical device meant for inhalation of medication for respiratory disorders.

Application field

The unit is designed mainly for home use.

User

Users are persons who suffer from respiratory disorders and require inhalation of medications.

Indications for use

This device is a compressor nebulizer intended to be used for inhaling medication for respiratory disorders.

Features (particularities)

- Unique nebulizer kit that can treat upper, mid and lower airways.
- Compliant with the ERS guidelines for Inhaled Therapies
- Designed for combined treatment of Asthma and associated upper Airways diseases.

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

EN 60601-1:2006

EN 60601-1-2:2007 3rd edition

EN 13544-1:2009

EN 60601-1-11:2010

EN 980:2008

EN 62366:2008

UNI EN ISO 10993-1:2010

EN 10993-5:2009

EN 10993-10:2010

EN 14971:2012

UNI EN 1041:2013

Description of the operating principle



Compressor nebulizer functions by air being pumped through a tube to a nebulizer kit that creates an aerosol of medication for the patient to inhale. Efficient dispersion of medication is the most important element of respiratory disease control. The A3 Complete compressor nebulizer is designed for persons using the device to easily inhale the medication prescribed by their doctor/care giver.

How to use the device

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

1. Carefully add medication to the nebulizer kit.
2. Connect air tube to the nebulizer kit and the compressor nebulizer.
3. Press the power switch to turn the nebulizer on.
4. Inhale medication as prescribed by your doctor.
5. Complete treatment, clean nebulizer kit

Technical Specifications

Product Description	Compressor Nebulizer
Model (-code)	A3 Complete (NE-C300-E)
Rating:	230V ~ 50 Hz
Power Consumption	140VA
Applied Part	 = Type BF
Protection against electric shock	Internally powered ME equipment (When using only the batteries)  = Class II ME equipment (AC adapter)
Operating temperature / Humidity	+10°C to +40°C Maximum: 10% to 95% RH
Storage Temperature / humidity / air pressure	-20°C to +70°C Maximum: 5% to 95% RH / 690 to 1060 hPa
Console Weight	Approx. 1.3 kg compressor only
Outer dimensions	Approx. 130 (w) mm x 215 (h) mm x 190 (l) mm
Package Content	Compressor, Nebulizer Kit, Air tube (PVC, 100 cm), Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), 3 pcs Spare Air Filters, Carrying Bag, Instruction Manual
EAN code:	401567210940 7

The device fulfills the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN13544-1:2007+A1:2009, Respiratory therapy equipment – Part 1: Nebulizing systems and their components.

Technical data for the OMRON A3 Complete Compressor with the A3 Complete nebulizer kit:

Appropriate Medication Quantities: 2 ml minimum - 12 ml maximum

Sound: Noise level (at 1 m distance) 65 dB

MMAD = Mass Median Aerodynamic Diameter

Result of cascade impactor measurements for particle size

	Nebulizer control ring in position 1	Nebulizer control ring in position 2	Nebulizer control ring in position 3
Particle Size (MMAD)	Approx. 10 μm	Approx. 5 μm	Approx. 3 μm
Nebulization Rate (by weight loss)	Approx. 0.7 ml/min	Approx. 0.5 ml/min	Approx. 0.3 ml/min
Aerosol Output (3 ml, 1% Naf)	Approx. 0.45 ml	Approx. 0.53 ml	Approx. 0.36 ml
Aerosol Output Rate (1% NaF)	Approx. 0.15 ml/min	Approx. 0.12 ml/min	Approx. 0.1 ml/min

Materials for main unit

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

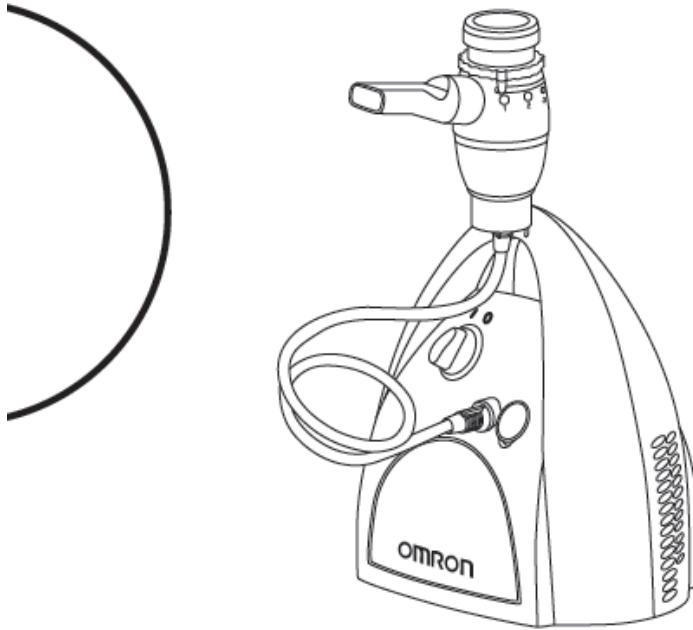
Materials for accessories

Item	Material
Nebulizer Kit	PP (polypropylene)
Air Tube	PVC (polyvinyl chloride) – phthalate free
Mouthpiece	PP (polypropylene)
Nosepiece	PP (polypropylene)
Adult Mask	PVC (polyvinyl chloride)– phthalate free
Child Mask	PVC (polyvinyl chloride)– phthalate free
Carrying Bag	TNT in PP (non-woven-fabric in polypropylene)

Title page - Instruction Manual

(10 languages – English / French / German / Italian / French / Spanish / Dutch / Russian / Arabic / Turkish)

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EN

Compressor Nebulizer A3 Complete (NE-C300-E)

Instruction Manual

All for Healthcare

IM-NE-C300-E-01-07/2014
3A3128 rev.00

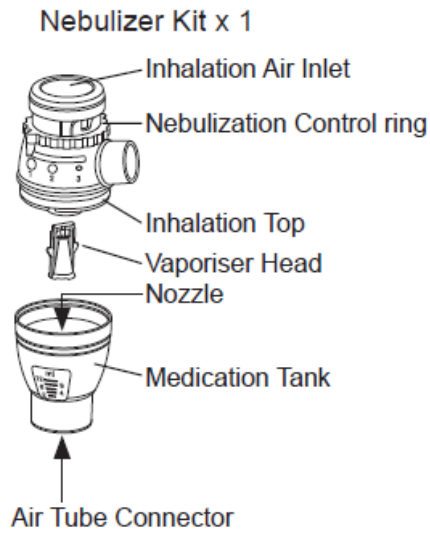
Packaging Design



Package specifications

Package	Amount	Approx. weight, g	Approx. dimensions W x D x H, mm
Main unit – not including Accessories	1	1.3 kg	130 x 190 x 215
Sales package	1	1.71 kg	205 x 148 x 238
Master Carton	4	7.7 kg	422 x 315 x 265

Optional Medical Accessories as a single package (NEB6001) (within the scope of EC Medical Device Directive 93/42/EEC)



Adult Mask (PVC) x 1



Child Mask (PVC) x 1



Mouthpiece x 1



Nosepiece x 1



Air Tube
(PVC, 100cm) x 1



Optional Non-Medical Accessories

Spare Air Filters x 3



Operation and Care

The device should be cleaned with a soft and dry cloth, or a soft and moistened cloth and neutral soap.

(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 disinfecting” section.

- Clean and disinfect the nebulizer kit, mask, mouthpiece or nosepiece 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.

Error Messages

Problem	Cause	Remedy
Nothing happens when the power switch is turned.	Is the power plug plugged into a power outlet?	Check that the plug is inserted in a power outlet. Unplug then reinsert the plug if necessary.
No nebulization or low nebulization rate, when the power is on.	Is there medication in the medication tank?	Add the correct amount of medication to the medication tank.
	Is there too much/little medication in the medication tank?	
	Is the vaporizer head missing or not assembled correctly?	Attach the vaporiser head correctly.
	Is the nebulizer kit assembled correctly?	Assemble the nebulizer kit correctly.
	Is the nozzle blocked?	Make sure that the nozzle is free of blockages.
	Is the nebulizer kit tilted at a sharp angle?	Make sure that the nebulizer kit is not tiled at an angle of more than 45 degrees.
	Is the air tube connected correctly?	Make sure that the air tube is correctly connected to the compressor and nebulizer kit.
	Is the air tube folded or damaged?	Make sure that the air tube does not contain kinks.
	Is the air tube blocked?	Make sure that the air tube is free of blockages.
	Is the air filter dirty?	Replace the air filter with a new one.
The compressor is abnormally loud.	Is the air filter cover attached correctly?	Attach the air filter cover correctly.

Problem	Cause	Remedy
The compressor is very hot.	Is the compressor covered?	Do not cover the compressor with any type of cover during use.
	Are the ventilation slots blocked?	Do not block the ventilation slots.

Warnings

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

(Usage)

- A single-patient use is recommended.
- Do not use the device for other use than nebulization for aerosol therapy. Manufacturer will not be held responsible for inappropriate use of the device.
- Use only original OMRON accessories as indicated in the instruction manual for this device.
- For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist. Before use check the position of the Nebulization Control ring.
- If you feel 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 or medication remaining inside.
- Do not use or store the device where it may be exposed to noxious fumes or volatile substances.
- Do not use the device where it may be exposed to flammable gas.
- Do not cover the compressor with a blanket, towel, or any other type of cover during use.
- Always dispose of any remaining medication after use, and use fresh medication each time.
- Do not use in anaesthetic or ventilator breathing circuits.
- Do not block the ventilation slots. Never place the device where the ventilation slots may be obstructed during operation.
- 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 with gauze or other absorbent material.
- 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.

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

(Usage)

- Provide close supervision when this device is used by, on, or near children or invalids.
- Make sure that the parts are attached correctly.
- Make sure that the air filter is correctly attached.
- Make sure that the air filter is clean. If the air filter has been used for more than 70 applications, replace it with a new one.
- Do not tilt the nebulizer kit at an angle of greater than 45 degrees in all directions or shake it while in use.
- Do not use or store the device while the air tube is creased.
- Use only original nebulizing parts, air tube, air filter and air filter cover.
- Do not add more than 12 ml of medication to the medication tank.
- Do not carry or leave the nebulizer kit while the medication tank contains medication.
- Do not leave the device unattended with infants or persons who cannot express their consent.
- This product should not be used on patients, who are unconscious or are not breathing spontaneously.
- Do not subject the device or the parts to any strong shocks such as dropping the device on the floor.
- Do not distort the vaporiser head, or jab the nozzle of the medication tank with a pin or any sharp object.
- Do not insert fingers or objects inside the compressor.
- Do not disassemble or attempt to repair the compressor or power cord.
- Do not leave the device or its parts in extreme hot or cold temperature, or under direct sunlight.
- Do not block the air filter cover.
- Do not use the device while sleeping or if drowsy.
- Approved for human use only.
- The compressor may become hot during operation.
- Do not touch the compressor for other than necessary operation such as turning off the power while nebulizing.
- To avoid the medication residue on the face, be sure to clean the user's face after removing the mask.
- To avoid injury to the nose mucosa, do not squeeze the nosepiece into the back of the nose.
- Make sure that the vaporiser head is correctly installed before use.
- Do not use a damaged nebulizer kit, mouthpiece or nosepiece.

(Risk of electrical shock)

- 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.
- Changes or modifications not

(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 disinfecting” section.

- 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.

General Safety Precautions:

- Inspect the device and parts before using them each time, and check that there are no problems. In particular, be sure to check the following:
 - That the nozzle or air tube are not damaged.
 - That the nozzle is not blocked.
 - That the compressor operates normally.
- When using this device, there will be some noise and vibration caused by the pump in the compressor. There will also be some noise caused by the emission of compressed air from the nebulizer kit. This is normal and does not indicate a malfunction.
- Operate the device only as intended. Do not use the device for any other purpose.
- Do not use the device at temperatures greater than +40°C.
- Make sure that the air tube is securely attached to the compressor and nebulizer kit, and does not come loose. Twist the air tube plug slightly when inserting it into the air tube connectors to avoid the air tube disconnecting during use.
- To completely isolate the device from the power source unplug the plug from the power source.

Disposal

As there is a risk of environmental pollution, follow your applicable national and local legal regulations regarding disposal or recycling of this equipment and batteries. Do not recycle patient attachments such as masks, mouthpiece, but dispose of them as instructed by your local regulations.

Transportation and Storage

Store the device and the components in a clean, safe location.

Storage and transportation:

Temperature range: -20 to 60°C (-4 to 140°F)

Humidity range: 10 to 95%RH

Atmospheric pressure: 500 to 1060hPa

Warranty

Warranty term for compressor nebulizer - 3 years.

Warranty term for accessories – 1 year

Lifetime

Lifetime of the compressor nebulizer - 5 years

Lifetime of accessories: 1 year

Lifetime of filters: 70 applications

Warranty terms are specified in the instruction manual.

Repair

Do not disassemble or attempt to repair the device or components. Consult your authorized OMRON retail outlet or distributor.

Servicing

It is generally recommended to have the device inspected every 2 years to ensure correct functioning.