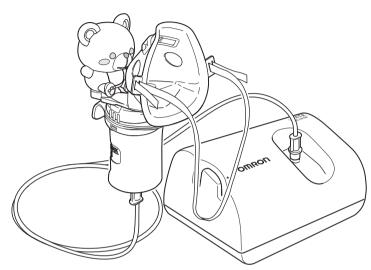
OMRON







Compressor Nebulizer NE-C801KD (NE-C801S-KDE(V))

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

• كتيب الارشادات

IM-NE-C801S-KDE(V)-06-04/2022

ΕN

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QUICK MANUAL

Please read entire manual before using the device.

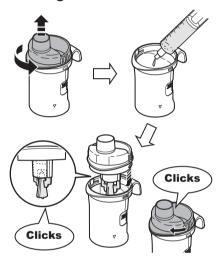
⚠ Warning:

Clean and disinfect all the parts before using them.

page 16-18



1. Adding medication



Rotate the inhalation top anti-clockwise to remove.

Add the appropriate amount of prescribed medication.

Make sure the vaporizer head is securely attached to the inhalation top.

Put the inhalation top back and rotate it clockwise until they click in place.

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2. Assembling kids accessory and mask



Assemble the nebulizer kit as the following order.

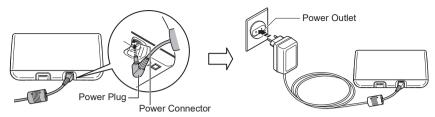
- [1] Cap
- [2] Kids accessory
- [3] Mask

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⚠ Warning:

Do not let infants and children play with a kids accessory. Kids accessory is not a toy, but a component of nebulizer kit.

3. Connecting AC adapter

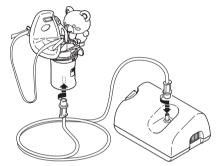


Insert the power plug of AC adapter into the power connector of the main unit.

Plug the AC adapter into the power outlet.

page 11

4. Attaching air tube

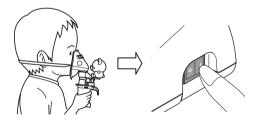


Attach the air tube to the main unit and to the nebulizer kit.

When do so, twist and push it firmly.

→ page 13

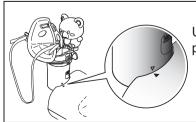
5. Applying mask and starting inhalation



Apply the mask securely.

Turn on the power to the main unit.

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Use the nebulizer kit holder to place the nebulizer kit

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Introduction

respiratory therapist.

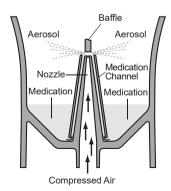
Thank you for purchasing the OMRON COMP AIR.

This product was developed in conjunction with respiratory therapists for the successful treatment of asthma, chronic bronchitis, allergies and other respiratory disorders. The compressor forces air to the nebulizer kit. When the air enters the nebulizer kit, it converts the prescribed medication into an aerosol of microscopic droplets that can easily be inhaled. This is a medical device. Operate the device only as instructed by your doctor and/or

NE-C801KD includes the kids accessory to enable children to feel more comfortable while inhaling. It improves compliance with drug treatment.

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 by being impacted to the baffle.



Intended use

Medical Purpose This product is intended to be used for inhaling medication for respiratory disorders. The compressor and its AC adapter are intended to be multiple patient multiple use. The nebulizer kit and its attachments are single patient multiple use. Intended User • Legally certified medical experts, such as doctor, nurse and therapist. • Caregiver or patient under the guidance of gualified medical experts for home treatment. • The user should also be capable of understanding general operation of NE-C801KD and the content of instruction manual. Intended Patients This product should not be used on 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. Durable period Durable periods are as follows, provided the product is used to nebulize 2 ml of medication 2 times a day for 6 minutes each time at room temperature (23°C). Durable period may vary depending on usage environment. Frequent use of the product may shorten the durable period. Compressor (Main unit) 5 years Nebulizer Kit 1 vear (Cap, Inhalation Top,

Vaporizer Head, Medication Tank)

Kids Accessory 1 vear Mouthpiece 1 year Air Tube (PVC, 100cm)/(Silicone, 100cm) 1 year Air Filter 60 days Mask (PVC)/(SEBS) 1 vear

Precautions for use

Warnings and cautions described in the instruction manual should be observed.

Important safety instructions

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

When using an electrical product, especially when children are present, basic safety precautions should always be followed including the following:

⚠ Warning:

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

(Usage)

- For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist.
- If you experience any allergic reactions or other difficulties 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 and kids accessory out of reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- Do not let infants and children play with a kids accessory. Kids accessory is not a toy, but a component of nebulizer kit.
- 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.
- Make sure that the nebulizer kit and kids accessory are clean before use.
- · Always dispose of any remaining medication after use, and use fresh medication each time.
- Do not use in anaesthetic or ventilator breathing circuits.
- Store the parts in a clean location to avoid infection.

(Risk of electrical shock)

- Do not use the compressor or AC adapter while they are wet, or connect them to a power outlet or other devices with wet hands.
- The compressor and the AC adapter are not waterproof. Do not spill water or other liquids on these parts. If liquid does spill on these parts, immediately unplug the AC adapter 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, such as a bathroom.
- Use only original OMRON AC adapter. Use of unsupported AC adapter may damage the device.
- Do not operate the device with a damaged power cord or plug.
- Keep the power cord away from heated surfaces.
- Read and follow the "Important information regarding Electromagnetic Compatibility (EMC)" (page 25) in the Technical Data Section.

(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 or mouthpiece 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 to dry on the parts.

↑ Caution:

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

(Usage)

- In order to prevent strangulation by the power cord or air tube, or injuries caused by mishandling, please 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 vaporizer head is correctly installed before use.
- 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 60 days, replace it with a new one.
- Do not spill liquid or medication on the compressor.
- 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 7 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.
- Do not subject the device or the parts to any strong shocks such as dropping on the floor.
- Do not distort the vaporizer 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 AC adapter.
- Do not leave the device or its parts where it will be exposed to extreme temperatures or changes in humidity, such as in a vehicle during the summer, or where it will be exposed to direct sunlight.
- · Do not block the air filter cover.
- · Do not use the device while sleeping or if drowsy.
- Do not block the slit between the cap and the inhalation air inlet.
- · Approved for human use only.
- If the device is used continuously, the service life of the device may be shortened.
- Limit use to 20 minutes at a time, and allow a 40 minute interval before using the device again.
- When using the device, the main unit may become hot.

- Do not touch the main unit for other than necessary operation such as turning off the power while nebulizing.
- To avoid the medication residue on the face, be sure to wipe the face after removing the mask.
- Do not use a damaged nebulizer kit or mouthpiece.
- While using this device, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields is within 30 cm. This may result in degradation of performance of the device.
- The nebulizer kit and its attachments are intended for use by a single patient. Do not use by multiple patients; Use separate accessories for each patient.

(Risk of electrical shock)

- · Always unplug the AC adapter 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.
- Always remove the AC adapter from the device after use and before cleaning.
- Do not misuse the power cord of AC adapter.
- Do not wind the power cord around the compressor or AC adapter.
- Changes or modifications not approved by OMRON HEALTHCARE will void the user warranty.
- Do not pull the power cord of AC adapter strongly.

(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 a fire.

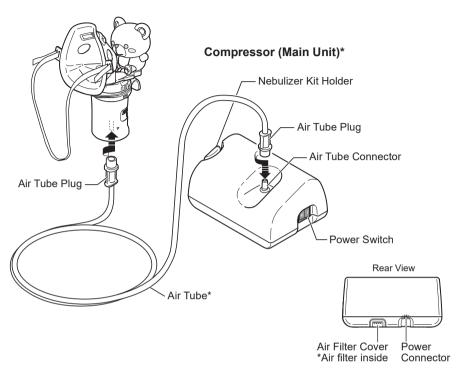
General Safety Precautions:

- 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 vaporizer head, nozzle, kids accessory 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.
- The AC adapter is provided so that the device can be completely isolated from the power source. To completely isolate the device from the power source unplug the plug from the power source.
- Read and follow the "Correct Disposal of This Product" in the Technical Data Section (page 25) when disposing of the device and any used accessories or optional parts.

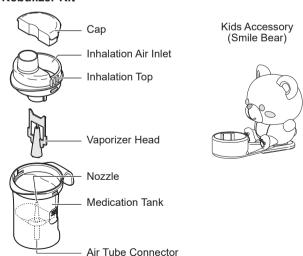
Keep these instructions for future reference.

1. Know your unit

Nebulizer Kit



Nebulizer Kit*



Other included items

Mouthpiece*



Child Mask (PVC)*



Infant Mask (PVC)*



Spare Air Filters × 5



AC Adapter Storage Bag Instruction Manual Warranty Card

* These parts comply with EN ISO 27427:2019

2. Preparing the nebulizer for use

⚠ Warning:

Clean and disinfect the nebulizer kit, mask or mouthpiece 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

For the instructions, refer to "Cleaning and disinfecting" section.

For directions on cleaning and disinfecting refer to Section 4 (page 16-18).

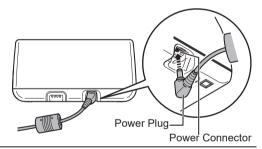
Note: Make sure that the air filter is changed regularly. Refer to Section 7 "Changing the air filter" (page 20).

2.1 Connecting AC adapter

1. Make sure that the power switch is turned off.

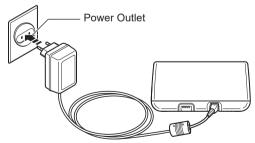
Check that the power switch is in the off (也) position.

Inserting the power plug of the AC adapter into the power connector on the compressor.



Plug the AC adapter into a power outlet.

- When disconnecting the AC adapter, unplug the AC adapter from the power outlet before removing the power connector on the compressor.
- Do not place the device in a location where it is difficult to disconnect the power cord.



2.2 Adding medication and assembling the parts

1. Remove the mask or mouthpiece, kids accessory and cap from the nebulizer kit.



- Remove the inhalation top together with vaporizer head from the medication tank.
 - 1) Rotate the inhalation top anti-clockwise.
 - **2)** Lift the inhalation top out of the medication tank.



3. Add the correct amount of prescribed medication to the medication tank.

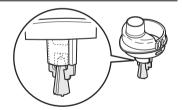
⚠ Caution:

The capacity of the medication tank is 2 to 7 ml.

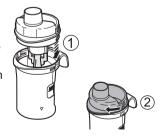
Note: Scales on the nebulizer kit are for reference only. The scale on the outside of the tank is with no vaporizer head in place. Please use the scale on your syringe or vial for accurate measurement of medication.



4. Make sure that the vaporizer head is securely attached to the inhalation top.



- Put the inhalation top back inside the medication tank.
 - 1) Align the protrusion on the inhalation top with the indent on the medication tank, as shown.
 - Rotate the inhalation top clockwise and align with the medication tank until they click in place.



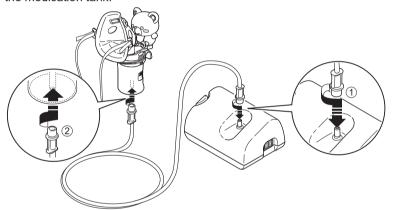
- Attach the cap, kids accessory, mask or mouthpiece to the nebulizer kit.
 - 1) Attach the cap to the inhalation air inlet.
 - 2) Attach the kids accessory to the inhalation top.
 - **3)** Attach the mask or mouthpiece to the inhalation top.

Note: If the amount of aerosol is too small, it is not necessary to place the cap.



7. Attach the air tube.

- Twist the air tube plug slightly and push it firmly into the air tube connector on the compressor.
- 2) Twist the air tube plug slightly and push it firmly into the air tube connector on the medication tank.



- 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.
- Take care not to spill the medication when attaching the air tube. Keep the nebulizer kit upright.

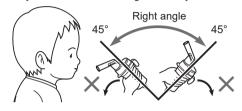
3. Taking medication

1. Hold the nebulizer kit as indicated on the right.

Follow the instructions of your doctor or respiratory therapist.

⚠ Caution:

Do not tilt the nebulizer kit at an angle of greater than 45 degrees in all directions. Medication may flow into the mouth or it may result in not nebulizing effectively.





2. Press the power switch to the on () position.

The compressor starts and nebulization starts.

Note: Observe whether aerosol is generated.

To stop nebulization

Press the power switch to the off (**b**) position.

⚠ Warning:

Do not cover the compressor with a blanket, towel, or any other type of cover during use.



- · Do not block the air filter cover.
- Limit use to 20 minutes at a time, and allow a 40 minute interval before using the device again.
- When using the device, the main unit may become hot.
- Do not touch the main unit for other than necessary operation such as turning off the power while nebulizing.

Note: Do not leave the compressor on for a long period of time. This could result in the compressor overheating or malfunctioning.

Inhale medication according to your doctor's and/or health care adviser's instructions.

Attach the mask so that it covers your nose and mouth and inhale the medication.

Exhale through the mask.

Using the mouthpiece

Insert the mouthpiece into your mouth and inhale the medication breathing normally.

Exhale as normal through the mouthpiece.



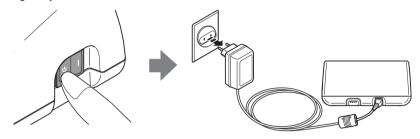


4. When treatment is complete, turn the power off. Check that there is no condensation or moisture in the air tube. Unplug the AC adapter from the power outlet and disconnect it from the compressor.

Note: Securely hold and press the power plug down to disconnect the AC adapter.

⚠ Caution:

Do not pull the power cord. Damage may be caused.

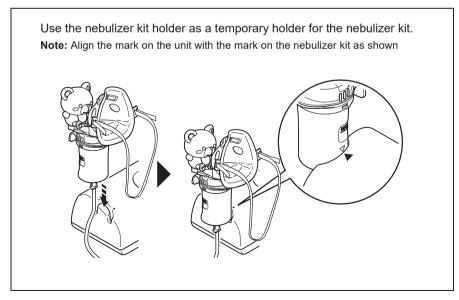


⚠ Warning:

Condensation may occur in the air tube. Do not store the air tube while it contains condensation or moisture. This could result in infection via bacteria.

If there is moisture or liquid remaining in the air tube, be sure to follow the procedure below to remove any moisture from within the air tube.

- 1) Make sure that the air tube is still connected to the air connector on the compressor.
- 2) Unplug the air tube from the nebulizer kit.
- 3) Turn on the compressor and pump air through the air tube to expel the moisture.



4. Cleaning and disinfecting

4.1 Cleaning

Clean the parts after each use to remove residual medication. This will avoid inefficient nebulization or infection.

■ Washable parts

 Nebulizer Kit (Inhalation top, Medication tank), Kids accessory, Masks, Mouthpiece, Air Tube (Silicone)

Wash them in warm water and mild detergent (neutral detergent). Rinse them thoroughly with clean hot tap water and allow to air dry in a clean place.

Vaporizer Head

Wash it with running water.

■ 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 detergent (neutral detergent).

Air Filter

Do not wash or clean the air filter. If the air filter becomes wet, replace it. Damp air filters can cause blockages.

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4.2 Disinfecting

Always disinfect the parts after the last treatment of the day. If the parts are heavily stained, replace them with new ones. It is expected to withstand 365 cycles of disinfection during its one-year durable period.

To select a method for disinfection, refer to the table on page 18.

⚠ Caution:

Do not use an autoclave, EOG gas sterilizer or low temperature plasma sterilizer.

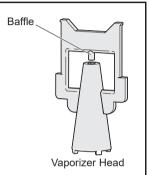
Note: The printing may come off the surfaces of kids accessory as a result of repeated washing and disinfecting.

Handling the Vaporizer Head

The vaporizer head is an important part that is used to vaporize medication.

Be sure to observe the following precautions when handling it.

- · Always wash the vaporizer head after each use.
- Do not use a brush or pin etc., to clean the parts.
- When disinfecting the parts by boiling, be sure to boil them in plenty of water.
- Do not boil vaporizer head together with other objects, other than applicable nebulizer accessories.
- Do not use a microwave oven, dish dryer or hair dryer to dry parts.



o: applicable X: not applicable

| Disinfacting | Parts | Mouthpiece | Nebulizer Kit | Air Tube (Silicone, 100cm) (optional) | Infant Mask (PVC) Child Mask (PVC) | Kids Accessory | Air Tube (PVC, 100cm) | Air Filter |
|---------------------|---|------------|----------------------------|---|--|-----------------------------|--------------------------|------------|
| Disinfecting method | Materials | А | PP (Vaporizer Head: PC) | Tube: Silicone Connector: PP | Mask: PVC (Phthalate free) Band: Rubber*** | PP, PVC (Phthalate free) | PVC (Phthalate free) | Polyester |
| | Alcohol Disinfecting ethanol | 0 | 0 | 0 | O** | Х | Х | Х |
| A | Sodium hypochlorite Milton* (0.1%, 15min.) | 0 | 0 | 0 | O** | 0 | Х | х |
| В | Boiling | 0 | 0 | 0 | Х | Х | Х | Х |



* an example of commercially available disinfectant. (The concentration and residence time specified in the table are under the conditions where the service life of the parts is tested with each disinfectant used as described in its instruction manual. Please note that the testing was not performed for the purpose of ensuring the effectiveness of the disinfectants. There is no intention of suggesting that such disinfectants be used. Conditions of use and ingredients of disinfectant vary for manufacturers. Please read the instruction manuals carefully before use and apply disinfectant to each part in

an appropriate way. Please notice that service life of the parts may be shorter depending on conditions, environments and frequency of use.)

** Remove the rubber band from mask before disinfecting.

***The band is not made with natural rubber latex.

A. Use a commercially available disinfectant. Follow the instructions provided by the disinfectant manufacturer

Note: Never clean with benzene, thinner or a flammable chemical.

B. Parts may be boiled between 15 to 20 minutes.

After boiling, carefully remove the parts, shake off excess water and allow to air dry in a clean environment.



5. 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 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.
- · Nebulizer kit should be replaced after using for one year.



6. Removing condensation from the air tube

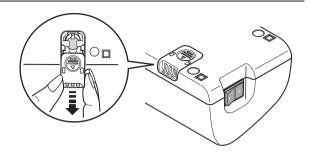
If there is moisture or liquid remaining in the air tube, be sure to follow the procedure below to remove any moisture from within the air tube.

- 1) Make sure that the air tube is connected to the air connector on the compressor.
- 2) Remove the air tube from the nebulizer kit.
- 3) Turn on the compressor and pump air through the air tube to expel the moisture.

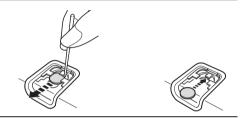
7. Changing the air filter

If the air filter has been used for more than 60 days, replace it with a new one.

1. Pull the air filter cover off the compressor.

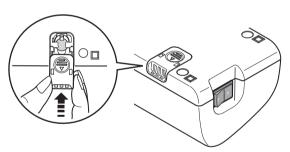


2. Change the air filter.



3. Put the air filter cover back in place.

Make sure it is attached properly.



- Use only OMRON air filters designed for this device. Do not operate without a filter.
- · There is no front or back orientation for the air filters.
- Check that air filters are clean and free of dust before inserting them.
- Do not wash or clean the filter. If the air filter becomes wet, replace it. Damp air filters can cause blockages.
- Please contact your OMRON dealer for additional air filters, or if the parts supplied with the device are damaged or missing.

8. Troubleshooting

If any of the below problems occur during use, first check that no other electrical device is within 30 cm. If the problem persists, please refer to the table below.

| Problem | Cause | Remedy | |
|--|---|--|--|
| Nothing happens when the power switch is pressed. | Is the AC adapter connected correctly to the an electrical outlet and the compressor? | Check that the plug is inserted in an electrical outlet. Unplug then reinsert the plug if necessary. | |
| No nebulization or low nebulization rate, when the | Is there medication in the medication tank? | Add the correct amount of medication to the medication tank. | |
| power is on. | Is there too much/little medication in the medication tank? | | |
| | Is the vaporizer head missing and not assembled correctly? | Attach the vaporizer 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 tilted 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 device is abnormally loud. | Is the air filter cover attached correctly? | Attach the air filter cover correctly. | |
| The device is very hot. | Is the compressor covered? | Do not cover the compressor with any type of cover during use. | |
| | Is the device operating continuously over 20 minutes? | Limit use to 20 minutes at a time, and allow a 40 minute interval before using the device again. | |

Note: If the suggested remedy does not solve the problem, do not try to repair the device - no parts of the unit are user serviceable.

Return the unit to an authorized OMRON retail outlet or distributor.

Technical data

Product Category: Nebulizers

Product Description: Compressor Nebulizer

Model (code): NE-C801KD (NE-C801S-KDE(V)) 100-240V ~ 350mA, 50/60Hz Rating (AC adapter):

Rating

(Compressor Nebulizer):

12V = 0.8A Operating Condition: Intermittent operation 20min. ON / 40min. OFF

Operating Temperature/ Humidity/Air Pressure:

+10°C to +40°C / 30% to 85% RH (non-condensing) / 700 to 1060 hPa

Storage and Transport Temperature/Humidity/ -20°C to +60°C / 10% to 95% RH (non-condensing) / 700 to 1060 hPa

Air Pressure:

Weight: Approx. 290g (compressor only)

Dimensions: Approx. 142 (W) × 72 (H) × 98 (D) mm (compressor only) Contents: Compressor, Nebulizer Kit, Kids Accessory (Smile Bear). Air Tube (PVC, 100cm), 5 pcs Spare Air Filters, Mouthpiece, Infant Mask (PVC), Child Mask (PVC), AC adapter, Storage Bag.

Instruction Manual, Warranty Card.

Classifications: Class II (Protection against electric shock).

Type BF (Applied part); Mouthpiece, Child Mask, Infant Mask

IP21 (Ingress Protection)

C € 0197

- 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.
- If the device is stored at the maximum or minimum storage and transport temperature and is moved to an environment with a temperature of 20°C, we recommend waiting for approximately 2 hours before
- Do not use the device where it may be exposed to flammable gas.
- This device fulfils the provisions of the European Standard EN13544-1:2007+A1:2009, Respiratory therapy equipment - Part1: Nebulizing systems and their components and EN ISO 27427:2019 Anaesthetic and respiratory equipment - Nebulizing systems and components.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. The compressor and the AC adapter are protected against solid foreign objects of 12 mm diameter and greater such as a finger, and against vertically falling water drops which may cause issues during a normal operation.
- Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

| Symbols description | | |
|---------------------|---|--|
| Ţ <u>i</u> | Need for the user to consult the instructions for use | |
| ☀ | Applied part - Type BF Degree of protection against electric shock (leakage current) | |

| | Symbols description |
|--------------------------------|---|
| (3) | Need for the user to follow this instruction manual thoroughly for your safety. |
| | Class II Protection against electric shock |
| IP XX | Ingress protection degree provided by IEC 60529 |
| C€ | CE Marking |
| UK CA | UKCA Marking |
| UDI | Unique device identifier |
| SN | Serial number |
| MD | Medical device |
| ~~ <u></u> | Date of manufacture |
| 1 | Temperature limitation |
| <u></u> | Humidity limitation |
| 6.6 | Atmospheric pressure limitation |
| О ог Ф | Power OFF or Stand-by |
| | Power ON |
| ♦-ⓒ- ♦ , ⊝- ● -⊕ | Indication of connector polarity |
| | Fuse |
| | For indoor use only |
| \sim | Alternating current |
| === | Direct current |
| TUV , EN 60601-1: | Certified by TÜV |
| (IV) | Efficiency Level of power supply |
| APD | The company logo of AC adapter supplier |
| 147 | The company logo of AC adapter supplier |
| COMP A-I-R | Trademark of OMRON compressor nebulizers (COMP A-I-R, COMP A-I-R basic, COMP A-I-R Elite, COMP A-I-R Pro) |

Technical data for the OMRON NE-C801KD Compressor with the OMRON V.V.T. (Virtual Valve Technology) Nebulizer kit:

Type of Medication Liquid: Solution, Suspension

Particle Size: **MMAD Approx. 3µm (2.5%NaF)

Medication Tank Capacity: 7ml maximum

Appropriate Medication 2ml minimum - 7ml maximum

Quantities:

Residual Volume:

Approx. 0.7ml

Sound: *Noise level (at 1 m distance) 46 dB

Nebulization Rate: *Approx. 0.3ml/min (by weight loss)

 Aerosol Output:
 **0.47ml (2.5ml, 1%NaF)

 Aerosol Output Rate:
 **0.06ml/min (2.5ml, 1%NaF)

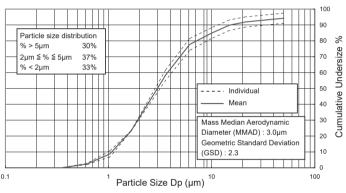
Percentage of Fill Volume

2.4%

Emitted Per Minute:

Result of cascade impactor measurements for particle size**

Cumulative % particle mass of sodium fluoride under 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

- Performance may vary with medication such as suspensions or high viscosity.
 See medication supplier's data sheet for further details.
- The particle size distribution and aerosol output may vary by combination of product, medication and ambient conditions such as temperature, humidity and atmospheric pressure.
- The disclosures for nebulizer performance are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric or infant populations.
- See web site of OMRON HEALTHCARE EUROPE to update technical information.
 URL: www.omron-healthcare.com

Important information regarding Electromagnetic Compatibility (EMC)

NE-C801S-KDE manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN60601-1-2:2015 Electromagnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual or at www.omron-healthcare.com

Refer to the FMC information for NF-C801S-KDF on the website.



Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

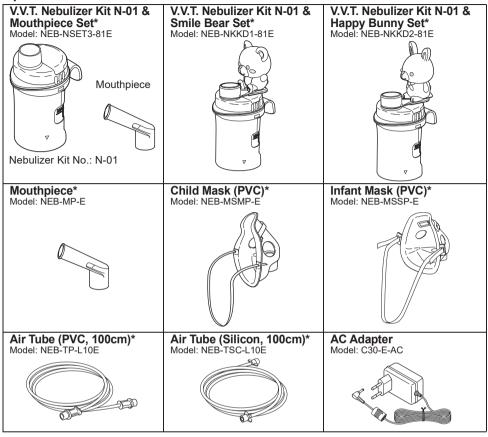
This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

10. Accessories and replacement parts

Optional Medical Accessories



^{*} These parts comply with EN ISO 27427:2019

Other Optional/Replacement Parts



| Manufacturer | OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN |
|---|--|
| EU-representati EC REP Importer in EU | OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com |
| Production facil | ity OMRON HEALTHCARE MANUFACTURING VIETNAM CO., LTD. No.28 VSIP II, Street 2, Vietnam-Singapore Industrial Park II, Binh Duong Industry-Services-Urban Complex, Hoa Phu Ward, Thu Dau Mot City, Binh Duong Province, Vietnam |
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