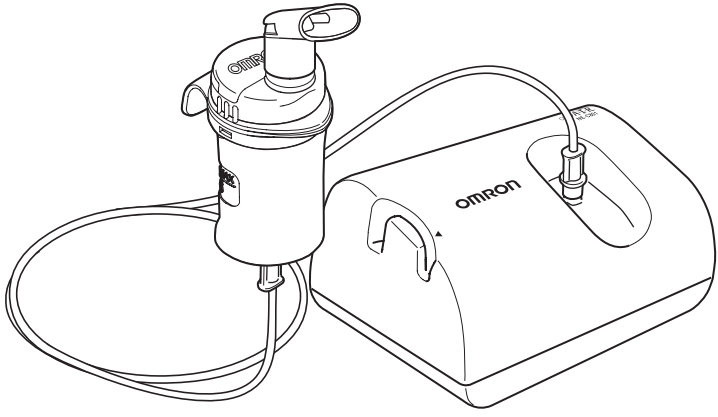
OMRON

INSTRUCTION MANUAL

COMP A-I-R™

Compressor Nebulizer
NE-C801



ESPAÑOL

ENGLISH

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner

CONTENTS

The illustrations shown in this instruction manual are image drawings and may differ slightly from the appearance of the actual product.

INTRODUCTION

Thank you for purchasing the OMRON NE-C801 Compressor Nebulizer.

Fill in for future reference.

DATE PURCHASED: _____

SERIAL NUMBER:_____

- *Staple your purchase receipt here*
- *Register your product on-line at www.register-omron.com*

This product was developed for the successful treatment of asthma, allergies and other respiratory disorders. The compressor forces air to the nebulizer. When the air enters the nebulizer, it converts the prescribed medication into an aerosol of microscopic droplets that can easily be inhaled.

Your NE-C801 Compressor Nebulizer comes with the following components:

- Compressor (Main Unit)
- Nebulizer Kit
- Mouthpiece
- Air Tube (PVC, 100 cm)
- AC Adapter
- Air Filters (Package of 5)
- Storage Bag
- Instruction Manual

The following are optional accessories sold separately:

- Nosepiece
- Adult Mask (PVC)
- Child Mask (PVC)

Please read this instruction manual thoroughly before using the unit.
Please keep for future reference.
For specific information about your own nebulizer,
CONSULT YOUR DOCTOR.

SAVE THESE INSTRUCTIONS

INTENDED USE

The NE-C801 Compressor Nebulizer System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The system is designed for use with pediatric (defined by the prescribed medication) and adult patients in the home, hospital, and sub-acute settings.

All warnings and cautions described in this manual should be observed.

SAFETY INFORMATION

To ensure the correct use of the product, basic safety measures should always be followed including the warnings and cautions listed in this instruction manual.

SAFETY SYMBOLS USED IN THIS INSTRUCTION MANUAL	
⚠ **WARNING**	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ **CAUTION**	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

OPERATING THE DEVICE

- ⚠ For type, dose, and regime of medication follow the instructions of your physician or licensed healthcare practitioner.
- ⚠ If you feel anything unusual during use, stop using the device immediately and consult your physician.
- ⚠ Do not cover the compressor with a blanket, towel, or any other type of cover during use. This could result in the compressor overheating or malfunctioning.
- ⚠ Do not use the device where the device may be exposed to flammable gas or vapors.
- ⚠ Do not use tap or mineral water in the nebulizer for inhaling purposes.
- ⚠ Clean and disinfect the nebulizer kit, mouthpiece, and optional nosepiece or optional masks before using them for the first time after purchase.
- ⚠ If the device has not been used for a long period of time, clean and disinfect the nebulizer kit, mouthpiece, and optional nosepiece or optional masks before using them.
- ⚠ Pentamidine is not an approved medication for use with this device.
- ⚠ Always dispose of any remaining medication in the medication cup after each use. Use fresh medication each time you use the device.
- ⚠ Do not leave the device or its parts where it will be exposed to extreme temperatures or changes in humidity, such as leaving the device in a vehicle during warm or hot months, or where it will be exposed to direct sunlight.
- ⚠ Do not use or store the device where it may be exposed to noxious fumes or volatile substances.
- ⚠ Make sure that the nebulizer kit is clean before use.
- ⚠ Do not use in anaesthetic or ventilator breathing circuits.
- ⚠ Not suitable for use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide.

SAFETY INFORMATION

OPERATING THE DEVICE (continued)

- ⚠ Do not operate where oxygen is being administered in a closed environment (such as an oxygen tent).
- ⚠ Provide close supervision when this device is used by, on, or near infants, children or compromised individuals.
- ⚠ 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 minutes 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.
- ⚠ Do not insert any object into the compressor.
- ⚠ Make sure the air filter is clean. If the air filter has changed color or has been used on average for more than 60 days, replace it with a new one.
- ⚠ Make sure the nebulizer kit is correctly assembled, the air filter is properly installed, and the air tube is correctly connected to the compressor and the nebulizer kit. Air may leak from the air tube during use if not securely connected.
- ⚠ Inspect the compressor (main unit) and the nebulizer parts each time before using nebulizer kit. Make sure no parts are damaged, the nozzle and air tube are not blocked and the compressor operates normally.
- ⚠ Do not use the device if the air tube is bent.
- ⚠ Do not block the air filter cover.
- ⚠ Do not alter the baffle, the nozzle in the medication cup or any part of the nebulizer kit.
- ⚠ Do not add more than 7mL of medication to the medication cup.
- ⚠ Do not operate the device at temperatures greater than +40˚C (+104˚F).
- ⚠ Do not tilt the nebulizer kit so the angle of the kit is greater than 45˚. Medication may flow into the mouth.
- ⚠ Do not shake the nebulizer kit while using the device.
- ⚠ Do not subject the compressor or any of the components to strong shocks, such as dropping on the floor.
- ⚠ This device is approved for human use only.
- ⚠ Do not disassemble or attempt to repair the device or components.
- ⚠ Operate the device only as intended. Do not use the device for any other purpose.

OPERATING THE DEVICE (continued)

- ⚠ Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- ⚠ Use only Omron authorized parts and accessories. Parts and accessories not approved for use with the device do not perform the expected specification or it may damage the unit.
- ⚠ Changes or modification not approved by Omron Healthcare will void the user warranty.
- ⚠ To avoid injury to the nose mucosa, do not squeeze the optional nosepiece into the back of the nose.
- ⚠ To avoid the medication residue on the face. After nebulization, be sure to wipe the face after removing the optional masks.
- ⚠ 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.
- ⚠ When sterilizing parts by boiling, make sure that the container does not boil dry.
- ⚠ Do not use the device while sleeping or if drowsy.
- ⚠ Do not block the slit between the cap and the inhalation air inlet.

RISK OF ELECTRICAL SHOCK

- ⚠ Do not connect the AC adapter terminal using wire or other metallic conductors.
- ⚠ Do not use the compressor (main unit) or AC adapter while they are wet.
- ⚠ Do not plug or unplug the AC adapter into the electrical outlet with wet hands.
- ⚠ Do not immerse the compressor (main unit) in water or other liquid.
- ⚠ Do not spill water or other liquids on the compressor and AC adapter. These parts are not waterproof. If liquid spills on these parts, immediately unplug the AC adapter and wipe off the liquid with gauze or other soft absorbent material.
- ⚠ Do not use or store the device in humid locations, such as a bathroom. Use the device within the operating temperature and humidity.
- ⚠ Use only the AC adapter designed by Omron for this device. Use of any other AC adapter may damage the device.
- ⚠ Do not operate the device with a damaged power cord or plug.
- ⚠ Do not use a cellular phone near the device. It may result in an operational failure.

SAFETY INFORMATION

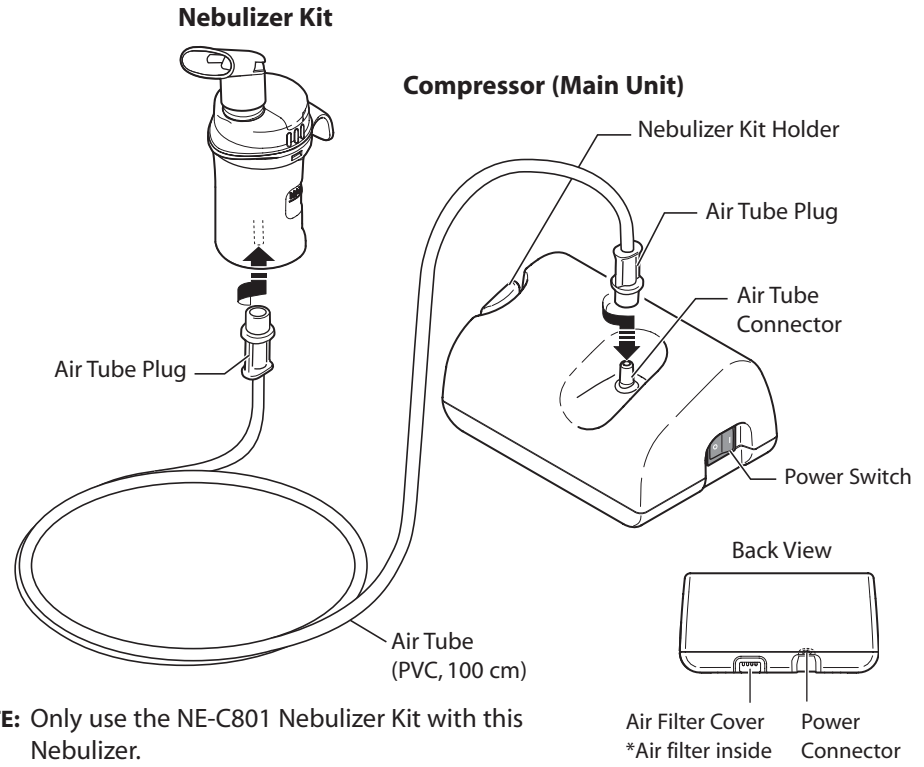
RISK OF ELECTRICAL SHOCK (continued)

- ⚠ Do not overload power outlets. Plug the AC adapter into the appropriate voltage outlet.
- ⚠ Do not use extension cords. Plug the AC adapter directly into the electrical outlet.
- ⚠ Unplug the AC adapter from the electrical outlet after using the device.
- ⚠ Remove the AC adapter from the device after use.
- ⚠ Unplug the AC adapter from the electrical outlet before cleaning the device.
- ⚠ Do not pull the power cord of AC adapter strongly.

MAINTENANCE AND STORAGE

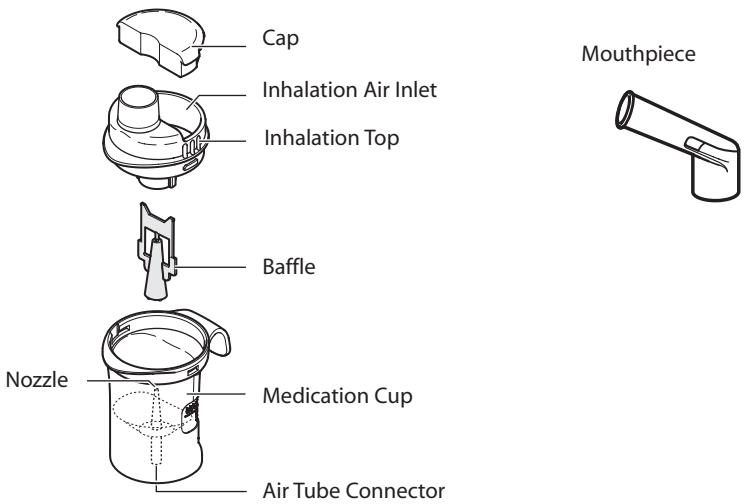
- ⚠ Keep the device out of the reach of unsupervised infants and children. The device may contain small parts that can be swallowed.
- ⚠ Do not leave the cleaning solution in the nebulizer parts. Rinse the nebulizer parts with clean hot tap water after disinfecting.
- ⚠ Wash the nebulizer parts after each use. Dry the parts immediately after washing.
- ⚠ Do not store the air tube with moisture or medication remaining in the air tube. This could result in infection as a result of bacteria.
- ⚠ Store the device and the components in a clean, safe location.
- ⚠ Do not carry or leave the nebulizer kit with medication in the medication cup.
- ⚠ Do not place or attempt to dry the device, components or any of the nebulizer parts in a microwave oven.
- ⚠ Do not wrap the power cord around the compressor (main unit) and AC adapter.

KNOW YOUR UNIT



NOTE: Only use the NE-C801 Nebulizer Kit with this Nebulizer.

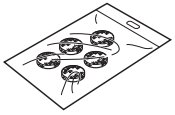
Nebulizer Kit



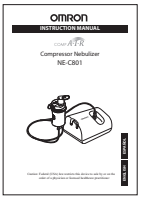
KNOW YOUR UNIT

Components:

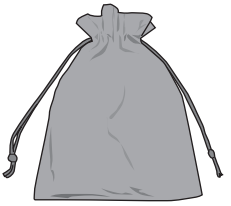
Air Filters
Package of 5



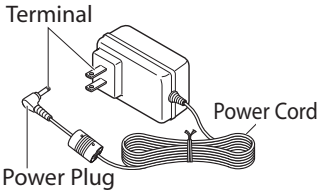
Instruction Manual



Storage Bag



AC Adapter



Accessories and Replacement Parts

	Model No.
AC Adapter	C30AC
Adult Mask (PVC)	9920
Child Mask (PVC)	9921
Air Filters (Package of 5)	C30FL
Air Filter Cover	C801FC
Air Tube (PVC, 100 cm)	C801AT
Nebulizer Kit Set	C801NEB
Includes Nebulizer Kit, Mouthpiece and Air Tube	
Nosepiece	C911
Mouthpiece	C910

PREPARING THE NEBULIZER FOR USE

⚠WARNING

- **Clean and disinfect the nebulizer kit, mouthpiece, and optional nosepiece or optional masks before using them for the first time after purchase.**
- **If the device has not been used for a long period of time, or if more than one person uses the same device, clean and disinfect the nebulizer kit, mouthpiece, and optional nosepiece or optional masks before using them.**

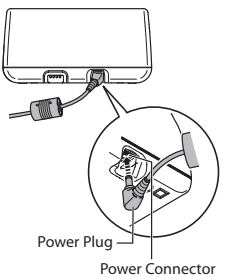
⚠CAUTION

Make sure the air filter is clean. If the air filter has changed color or has been used on average for more than 60 days, replace it with a new one.

For directions on cleaning and disinfecting refer to page 18 - 19.

For directions on changing the air filter refer to page 20.

1 Insert the power plug on the AC adapter into the power connector on the back side of the compressor. Plug the AC adapter into the electrical outlet.

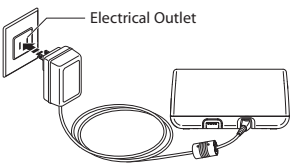


⚠WARNING

Do not plug or unplug the AC adapter into the electrical outlet with wet hands.

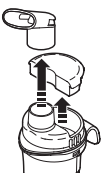
⚠CAUTION

- **Do not overload power outlets. Plug the AC adapter into the appropriate voltage outlet.**
- **Do not use extension cords. Plug the AC adapter directly into the electrical outlet.**



NOTE: AC adapter can be worked at 100 - 240V ~ 350mA, 50/60 Hz.

2 Lift up the mouthpiece and the cap to remove them from the nebulizer kit.



PREPARING THE NEBULIZER FOR USE

3 Rotate the inhalation top counterclockwise (A) and lift (B) to remove the inhalation top from the medication cup.

4 Add the correct amount of prescribed medication to the medication cup.

⚠WARNING

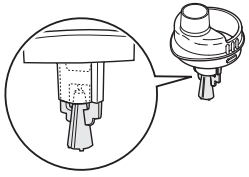
- **For type, dose, and regime of medication follow the instructions of your physician or licensed healthcare practitioner.**
- **Do not spill water or other liquids on the compressor and AC adapter. These parts are not waterproof. If liquid spills on these parts, immediately unplug the AC adapter and wipe off the liquid with gauze or other soft absorbent material.**
- **Do not use tap or mineral water in the nebulizer for inhaling purposes.**

⚠CAUTION

Do not add more than 7mL of medication to the medication cup.

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

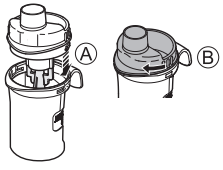
5 Make sure that the baffle is securely attached to the inhalation top.



6 Place the inhalation top on the medication cup.

Align the protrusion on the inhalation top with the indentation on the medication cup as illustrated (A).

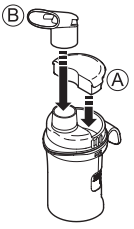
Turn the inhalation top clockwise until securely closed (B).



PREPARING THE NEBULIZER FOR USE

7 Attach the desired inhalation accessory.

USING THE MOUTHPIECE



Place the cap on the medication cup over the inhalation air inlet (A).

Attach the mouthpiece (B).

NOTE: Place the cap on the medication cup when using the mouthpiece. Using the cap with the mouthpiece will reduce the amount of medication that is discharged into the air.

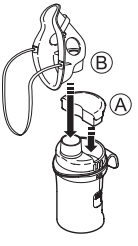
USING THE NOSEPIECE (Optional)

Place the cap on the medication cup over the inhalation air inlet (A).

Attach the nosepiece (B).

NOTE: Place the cap on the medication cup when using the nosepiece. Using the cap with the nosepiece will reduce the amount of medication that is discharged into the air.

USING THE CHILD MASK (Optional)

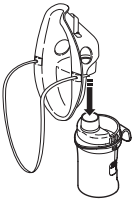


Place the cap on the medication cup over the inhalation air inlet (A).

Attach the child mask (B).

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

USING THE ADULT MASK (Optional)



Attach the adult mask to the inhalation top.

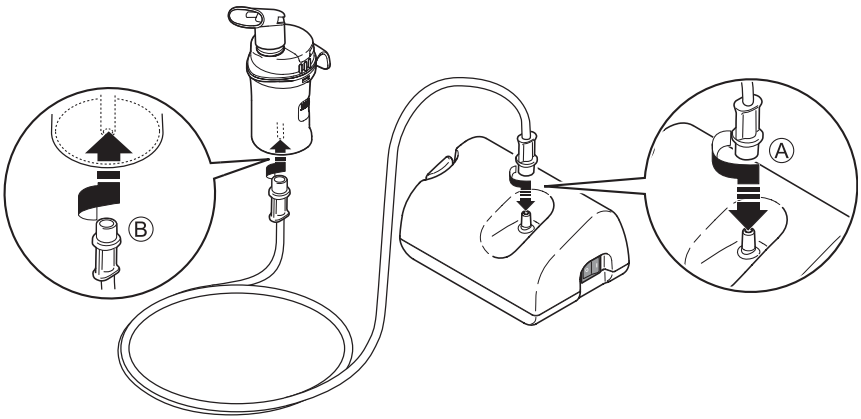
NOTE: If the amount of aerosol is too much, place the cap on the medication cup over the inhalation air inlet.

ATTACHING THE AIR TUBE

1 Twist the air tube plug slightly and push it firmly into the air tube connector on the upper side of the compressor (A).

2 Twist the air tube plug slightly and push it firmly into the air tube connector on the bottom of the nebulizer kit (B).

NOTE: Keep the nebulizer kit upright when attaching the air tube. Medication may spill out of the medication cup.

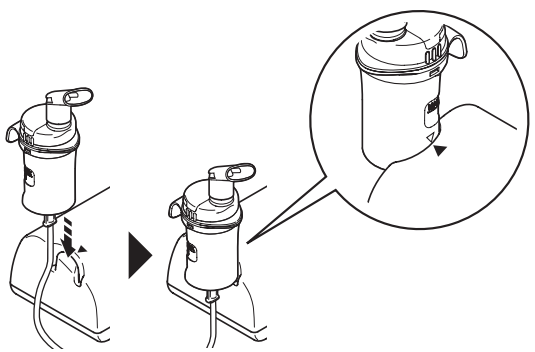


⚠CAUTION

- **Make sure the nebulizer kit is correctly assembled, the air filter is properly installed, and the air tube is correctly connected to the compressor and the nebulizer kit. Air may leak from the air tube during use if not securely connected.**
- **Do not use the device if the air tube is bent.**

3 Use the nebulizer kit holder as a temporary holder for the nebulizer kit.

NOTE: Align the mark on the unit with the mark on the nebulizer kit as shown.



USING THE DEVICE

⚠WARNING

- **Do not use the device where the device may be exposed to flammable gas or vapors.**
- **Do not use or store the device in humid locations, such as a bathroom. Use the device within the operating temperature and humidity.**

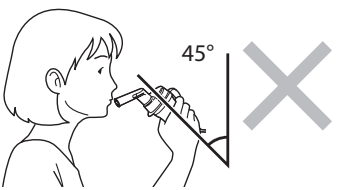
⚠CAUTION

- **Provide close supervision when this device is used by, on, or near infants, children or compromised individuals.**
- **Do not use a cellular phone near the device. It may result in an operational failure.**
- **Inspect the compressor (main unit) and the nebulizer parts each time before using the device. Make sure no parts are damaged, the nozzle and air tube are not blocked and the compressor operates normally.**

1 Hold the nebulizer kit as illustrated on the right.

⚠CAUTION

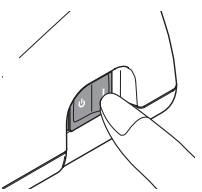
- **Do not tilt the nebulizer kit so the angle of the kit is greater than 45˚. Medication may flow into the mouth.**
- **Do not shake the nebulizer kit while using the device.**



2 Turn the power switch to the on (|) position.

As the compressor starts, nebulization begins and aerosol is generated.

To stop nebulization, turn the power switch to the off (⏻) position.



⚠WARNING

Do not cover the compressor with a blanket, towel, or any other type of cover during use. This could result in the compressor overheating or malfunctioning.

USING THE DEVICE

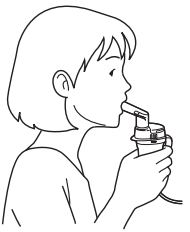
⚠CAUTION

- **Do not block the air filter cover.**
- **Limit use to 20 minutes at a time, and allow a 40 minutes 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.**

3 Inhale medication as instructed by your physician or licensed healthcare practitioner.

USING THE MOUTHPIECE

Insert the mouthpiece into your mouth. Inhale medication breathing normally. Exhale normally through the mouthpiece.

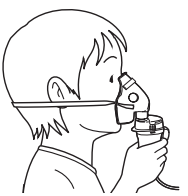


USING THE NOSEPIECE (Optional)

Inhale the medication through the nosepiece as illustrated. Exhale through the mouth.

USING THE CHILD MASK or THE ADULT MASK (Optional)

Place the mask over the nose and mouth. Pull the elastic strap over the head. Gently pull on the strap to secure the mask over the nose and mouth. Inhale the medication. Exhale normally through the mask.

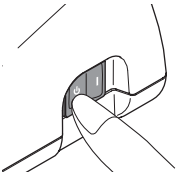


4 Complete the treatment.

⚠WARNING

For type, dose, and regime of medication, follow the instructions of your physician or licensed healthcare practitioner.

5 Turn the power switch to the off (⏻) position.
The compressor turns off and nebulization stops.



6 Disconnect the air tube from the nebulizer kit.
Hold the air tube plug and gently pull down to disconnect the air tube plug from the air tube connector on the bottom of the nebulizer kit.

7 Check the air tube. No condensation or moisture should remain in the air tube.

> **⚠WARNING**
>
> **Do not store the air tube with moisture or medication remaining in the air tube. This could result in infection as a result of bacteria.**

If any condensation or moisture remains in the air tube, remove the moisture from the air tube. Follow the directions below:

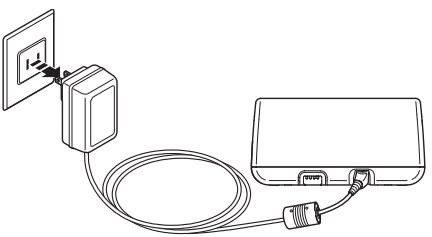
1. Make sure the air tube is still connected to the air tube connector on the upper side of the compressor.
2. Press the power switch on. The compressor will start and pump air through the air tube to expel the moisture.
3. Press the power switch again to turn the compressor off.

8 Disconnect the air tube from the compressor. Hold the air tube plug and gently pull the air tube plug off the air tube connector on the upper side of the compressor.

9 Unplug the AC adapter from the electrical outlet.

⚠CAUTION

- **Unplug the AC adapter from the electrical outlet after using the device.**
- **Remove the AC adapter from the device after use.**
- **Do not pull the power cord of AC adapter strongly.**

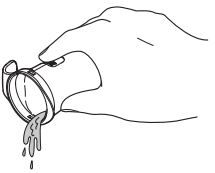


CLEANING AFTER EACH USE

Following cleaning instructions after each use will prevent any remaining medication in the bottle from drying resulting in the device not nebulizing effectively and will help prevent infections.

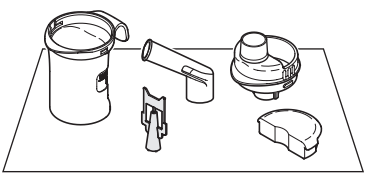
> **⚠WARNING**
>
> **Wash the nebulizer parts after each use. Dry the parts immediately after washing.**

1. Remove the inhalation accessory (mouthpiece, optional masks, or optional nosepiece) from the nebulizer kit.
2. Disconnect the air tube from the nebulizer kit.
3. Gently twist the inhalation top counterclockwise and lift to separate the nebulizer into two sections.
4. Discard remaining medication in the medication cup.



> **⚠WARNING**
>
> **Always dispose of any remaining medication in the medication cup after each use. Use fresh medication each time you use the device.**

5. Rinse all the parts with hot tap water.
6. Hand dry or air dry in a clean environment using a soft, clean, lint-free cloth.
7. Assemble the nebulizer kit and store it in a dry bag.



DAILY DISINFECTING

Disinfect the nebulizer kit and mouthpiece, or optional masks or optional nosepiece after the last treatment of the day.

To disinfect the parts, use one of the methods described below:

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

1 Submerge the parts in the cleansing solution for the specified period.

2 Remove the parts and discard the solution.

3 Rinse the parts with clean hot tap water, shake off excess water and allow to air dry in a clean environment.

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.

NOTE: Do not boil air tube, air filter, air filter cover and optional masks.

⚠CAUTION

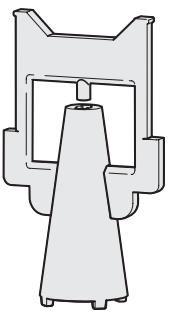
Do not use an autoclave, EOG gas disinfection or low temperature plasma sterilizer to disinfect the device.

Handling the Baffle

The baffle is an important part that is used to nebulize medication.
Be sure to observe the following precautions when handling it.

⚠CAUTION

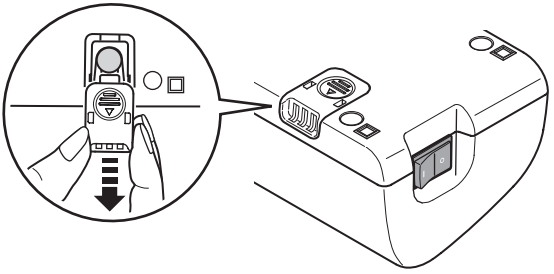
- **Always wash the baffle after each use.**
- **Do not use a brush or pin etc., to clean the parts.**
- **When disinfecting the parts by boiling, be sure to boil them in plenty of water.**
- **Do not boil the baffle together with other objects, other than applicable nebulizer accessories.**
- **Do not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



CHANGING THE AIR FILTER

If the air filter has changed color or has been used on average for more than 60 days, replace it with a new one. If water or medication has spilled on the air filter, replace with a new air filter immediately.

1 Pull the air filter cover to remove from the back side of the compressor.



2 Remove the dirty air filter.

⚠CAUTION

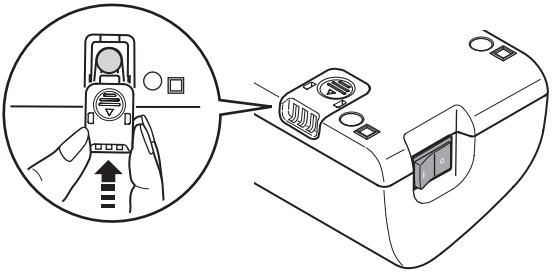
- **Do not attempt to wash or clean the air filter. Damp air filters can cause blockages. Do not substitute cotton or any other material for the air filter.**
- **Wash the air filter cover regularly to prevent any blockage in the cover. Do not boil. Make sure the cover is dry before inserting the new air filter.**

3 Insert a new air filter.

⚠CAUTION

Before inserting the new air filter make sure the air filter is clean and free of dust. Do not operate the device without the air filter. Use only the Omron air filter designed for this device.

4 Put the air filter cover back on the compressor.



CARING FOR THE DEVICE

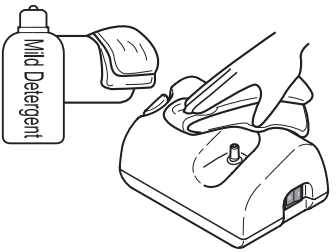
To keep your device in the best condition and protect the unit from damage, follow these directions:

⚠CAUTION

- **Do not subject the compressor or any of the components to strong shocks, such as dropping on the floor.**
- **Use only Omron authorized parts and accessories. Parts and accessories not approved for use with the device do not perform the expected specification or it may damage the unit.**

CLEANING THE COMPRESSOR

Clean the casing of the main unit by using a soft cloth moistened with water or a mild detergent. Do not use abrasive cleaners. Dry the casing immediately using a soft clean cloth.



⚠WARNING

Do not immerse the compressor (main unit) in water or other liquid.

⚠CAUTION

- **Unplug the AC adapter from the electrical outlet before cleaning the device.**
- **Do not insert any object into the compressor.**

STORING THE DEVICE

Place the compressor, the nebulizer kit and the inhalation accessory (air tube, mouthpiece, optional masks and optional nosepiece) in the storage bag. Store it in a safe, clean location.

⚠WARNING

- **Do not leave the device or its parts where it will be exposed to extreme temperatures or changes in humidity, such as leaving the device in a vehicle during warm or hot months, or where it will be exposed to direct sunlight.**
- **Keep the device out of the reach of unsupervised infants and children. The device may contain small parts that can be swallowed.**

⚠CAUTION

- **Do not carry or leave the nebulizer kit with medication in the medication cup.**
- **Do not wrap the power cord around the compressor (main unit).**

TROUBLESHOOTING GUIDE

PROBLEM	CAUSE	SOLUTION
No power to unit when the power switch is on.	The AC adapter is not plugged into an electrical outlet.	Turn the power switch off. Plug the AC adapter into an electrical outlet. Turn the device on.
No nebulization or low nebulization rate when the power is on.	No medication in the medication cup. Too much or too little medication in the medication cup.	Add the correct amount of prescribed medication to the medication cup.
	The baffle is not attached to the inhalation top or incorrectly positioned.	Make sure the baffle is correctly attached to the inhalation top.
	The nebulizer kit is not correctly assembled.	Make sure the nebulizer kit is correctly assembled and the inhalation accessory is correctly attached.
	The nozzle is blocked.	Clean and disinfect the nebulizer kit to remove the blockage.
	The nebulizer kit is tilted at an incorrect angle.	Hold the nebulizer kit correctly. Do not tilt the nebulizer kit so the angle of the kit is greater than 45 degrees.
	The air tube is incorrectly attached.	Make sure the air tube is correctly attached to the compressor and the nebulizer kit.
	The air tube is folded or damaged. The air tube is blocked.	Make sure the air tube is not folded, kinked or bent. Inspect the air tube for any damage. Replace the air tube if damaged.
	The air filter is dirty.	Replace the air filter with a new clean air filter.
The device is abnormally loud.	The air filter cover is incorrectly attached.	Attach the air filter cover correctly. Make sure the air filter cover is not blocked.
The device is very hot.	The compressor is covered.	Do not cover the compressor with any type of cover during use.
	Operating continuously over 20 minutes.	Limit use to 20 minutes at a time and allow a 40 minutes interval before using the device again.

LIMITED WARRANTY

Your OMRON NE-C801 Compressor Nebulizer, excluding the nebulizer kit, inhalation accessories, air tube and air filters, is warranted to be free from defects in materials and workmanship appearing within 3 years from the date of purchase, when used in accordance with the instructions provided with the compressor nebulizer. The above warranties extend only to the original retail purchaser.

We will, at our option, repair or replace without charge any compressor nebulizer covered by the above warranties. Repair or replacement is our only responsibility and your only remedy under the above warranties.

To obtain warranty service contact Customer Service by calling **1-800-634-4350** for the address of the repair location and the return shipping and handling fee.

Enclose the Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY OMRON IN CONNECTION WITH THIS PRODUCT, AND OMRON HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.

OMRON SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS, EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction. Because of special local requirements, some of the above limitations and exclusions may not apply to you.

FCC STATEMENT

NOTE: POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)

This product has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. The product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the product and the receiver.
- Connect the product into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for Canada only)

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled “Digital Apparatus”, ICES-003 of the Canadian Department of Communications.

Cet appareil numérique respecte les limites de bruits radioeléctriques applicables aux appareils numériques de Clase B prescrites dans la norme sur le materiel brouilleur: “Appareils Numériques”, ICES-003 édictée par le minister des communications.

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

SPECIFICATIONS

Model:	NE-C801 (NE-C801S-Z)
Type:	Compressor nebulizer
Rating (AC adapter):	100 - 240V ~ 350mA, 50/60 Hz
Rating (Compressor Nebulizer):	12V⎓0.8A
Nebulization Rate:	Approx. 0.3 mL/min (without cap)
Particle Size:	*MMAD approx. 3 µm (based on EN13544-1:2007)
Medication Cup Capacity:	7 mL (cc) max.
Appropriate Medication Quantities:	2 mL - 7 mL (cc)
Operating Condition:	Intermittent operation 20 min. ON/40 min. OFF
Operating Temperature/ Humidity:	+10°C to +40°C (+50°F to +104°F), 30% to 85% RH
Storage Temperature/ Humidity/Air Pressure:	–20°C to +60°C (–4°F to +140°F), 10% to 95% RH 700 hPa to 1060 hPa
Weight:	Approx. 9.5 oz. (270 g) (compressor only)
Dimensions:	Approx. 5 5/8" (w) × 2 7/8" (h) × 3 7/8" (d) (142 mm × 72 mm × 98 mm)
Contents:	Compressor, Nebulizer Kit, Air Tube (PVC, 100 cm), Mouthpiece, Air Filters (Package of 5), AC Adapter, Storage Bag and Instruction Manual.
Classification:	Class II equipment, Type B applied part

*MMAD = Mass Median Aerodynamic Diameter

 = Class II equipment

 = Type B applied part

 Read the instruction manual carefully

 = No operation

 = Power on

NOTES:

- Subject to technical modification without prior notice.
- Please note that nebulization rate and particle size may vary with medication type used.
- Parts and accessories not approved for use do not meet these specifications.
- Do not use the device where it may be exposed to flammable gas.
- This unit conforms to EMC Standard IEC60601-1-2. However, if it is used together with other medical devices or electrical equipment, they may influence the operations of one of devices. Please follow any instructions in the manuals and use all devices correctly.
- With respect to electric shock and mechanical hazards only in accordance with IEC60601-1.

TECHNICAL DATA

Particle Specifications

A series of aerosol performance tests were performed using an 8 stage cascade impactor at a sampling flow rate of 15 l/min equipped with a USP <601> induction port throat. Aerosol was sampled directly from the outlet. Three (3) device samples were tested with 3 runs each, for a total of 9 sample points per each drug.

The specifications are listed below with intervals given for a 95% confidence level.

Mean / Std. Dev	Pulmicort® (250µg/mL)	Intal® (10mg/mL)	Salbutamol® (5mg/mL)
Total Delivered Dose (µg)	391.11 ± 16.51	12368.89 ± 269.61	7883.33 ± 116.96
Total Delivered Dose Fraction (%)	78.2% ± 3.3%	61.8% ± 3.1%	77.0% ± 2.5%
Particle size (MMAD) µm	3.88 ± 0.28	2.91 ± 0.14	2.54 ± 0.28
Geometric Standard Deviation	1.93 ± 0.20	2.27 ± 0.02	2.62 ± 0.03
Respirable Fraction (0.5-5µm)	61.9% ± 4.0%	70.5% ± 1.3%	66.4% ± 1.6%
Total Respirable Dose (µg between 0.5-5µm)	242.17 ± 18.90	8729.49 ± 497.57	5235.02 ± 233.61
Medication Captured on USP Throat	13.34 ± 3.40	253.66 ± 27.42	144.94 ± 16.32
Medication Captured on USP Throat Fraction (%)	3.4% ± 0.4%	2.0% ± 0.1%	1.8% ± 0.1%
Medication Retained in Device	96.11 ± 9.61	8000.00 ± 438.21	2072.22 ± 257.90
Medication Retained in Device Fraction (%)	19.2% ± 1.9%	40% ± 2.2%	41.4% ± 5.2%
Coarse Particle Fraction (%) (>4.7µm)	37.1% ± 2.9%	27.7% ± 1.5%	26.6% ± 2.3%
Fine Particle Fraction (%) (<4.7µm)	59.6% ± 3.5%	70.2% ± 1.5%	71.6% ± 2.3%
Ultra-Fine Particle Fraction (%) (<1.0µm)	3.5% ± 1.7%	8.9% ± 2.1%	16.9% ± 5.3%

NOTE: Course particles (oro-pharyngeal deposition) and ultra-fine particles (exhaled) are not likely to deposit in the patient's airway and thus provide limited clinical benefit.

GUIDANCE AND MANUFACTURER'S DECLARATION

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.
Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by OMRON HEALTHCARE conform to this IEC60601-1-2 standard for both immunity and emissions.
Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by OMRON, with the exception of cables sold by OMRON as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

The NE-C801 is intended for use in the electromagnetic environment specified below. The customer or the user of the NE-C801 should assure that it is used in such environment.

Electromagnetic emissions IEC60601-1-2		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The NE-C801 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NE-C801 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic immunity IEC60601-1-2			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines *1)	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the NE-C801 requires continued operation during power mains interruption, it is recommended that the NE-C801 be powered from an uninterruptible power supply or battery.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	<5 % U_T (95 % dip in U_T) for 5 sec.	<5 % U_T (95 % dip in U_T) for 5 sec.	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			
*1) The test of input/output lines is not applicable since they are shorter than 3.0m.			

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic immunity IEC60601-1-2			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz ~ 80 MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the NE-C801 including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,*2) should be less than the compliance level in each frequency range.*3) Interference may occur in the vicinity of equipment marked with he following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

*2) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NE-C801 is used exceeds the applicable RF compliance level above, the NE-C801 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NE-C801.

*3) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

GUIDANCE AND MANUFACTURER'S DECLARATION

Recommended separation distance between portable and mobile RF communications equipment and the NE-C801

The NE-C801 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of the NE-C801 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NE-C801 as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	**Separation distance according to frequency of transmitter in meter**		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	***80 kHz to 800 MHz*** $d = 1.2\ \sqrt{P}$	***800 MHz to 2.5GHz*** $d = 2.3\ \sqrt{P}$
0.01	0.12	*0.12*	*0.23*
0.1	0.38	*0.38*	*0.73*
1	1.2	*1.2*	*2.3*
10	3.8	*3.8*	*7.3*
100	12	*12*	*23*

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

EMC tests have included the AC adapter as included with the product.

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