

Compressor Nebulizer Model NE-C101 Instruction Manual

EN

Intended use

Medical Purpose

This product is intended to be used for inhaling medication for respiratory disorders.

Intended User

- Legally certified medical experts, such as doctor, nurse and therapist.
- Caregiver or patient under the guidance of qualified medical experts for home treatment.
- The user should also be capable of understanding general operation of NE-C101 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 saline 3 times a day for 10 minutes each time at room temperature (23°C).

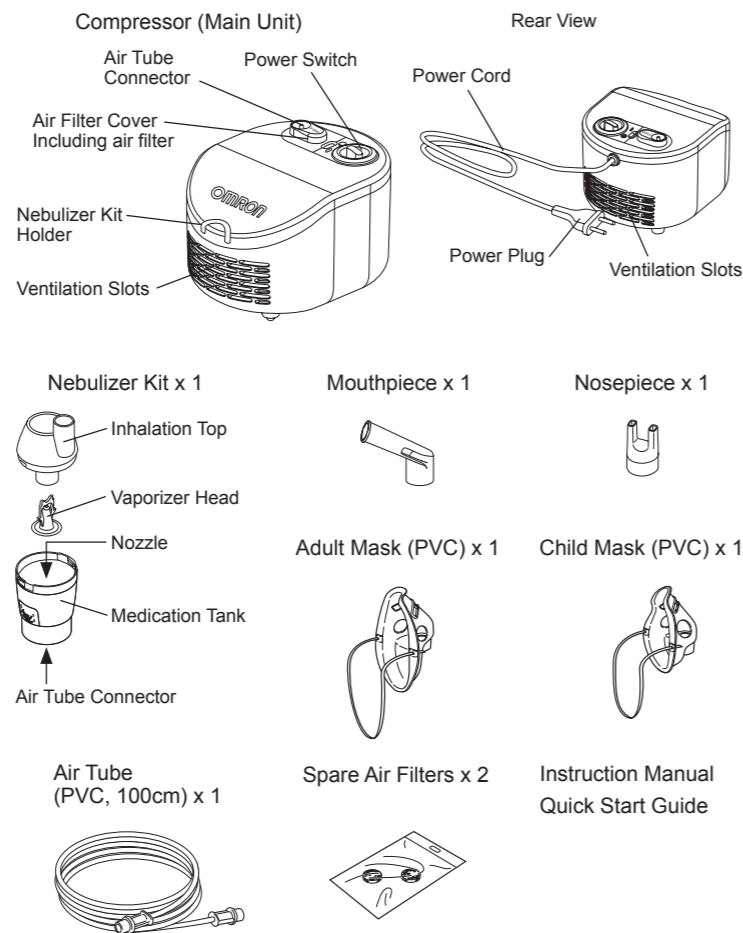
Durable period may vary depending on usage environment. Frequent use of the product may shorten the durable period.

Compressor (Main unit)	5 years
Nebulizer Kit	1 year
Mouthpiece	1 year
Nosepiece	1 year
Air Tube (PVC)	1 year
Air Filter	60 days
Mask (PVC)	1 year

Precautions for use

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

Know your unit



All for Healthcare

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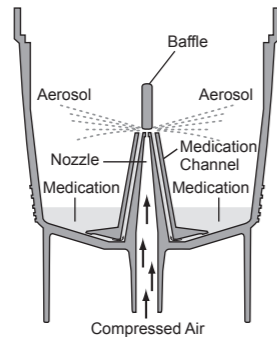
Thank you for purchasing the NE-C101.

This product was developed in conjunction with respiratory therapists for the successful treatment of asthma, chronic bronchitis, allergies and other respiratory disorders.

This is a medical device. Operate the device only as instructed by your doctor and/or respiratory therapist.

How the nebulizer kit works

The medication that is pumped up through the medication channel is mixed with compressed air which is generated by a compressor pump. The compressed air mixed with medication is turned into fine particles and sprayed when in contact with the baffle.



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EU representative	OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com
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Asia Pacific HQ	OMRON HEALTHCARE SINGAPORE PTE LTD. 438A Alexandra Road, #05-05/08 Alexandra Technopark, Singapore 119967 www.omronhealthcare-ap.com

Made in Vietnam

Important safety instructions

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

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

(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.
- Always dispose of or reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- 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. The compressor could get hot and there is a possible risk of a burn if touched.
- 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. The compressor could get hot and there is a possible risk of a burn if touched.
- Store the parts in a clean location to avoid 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.

(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 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 being used by, 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 has been used for more than 60 days, replace it with a new one.
- Do not tilt the nebulizer kit at an angle of greater than 30 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.
- Do not subject the device 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 power cord.
- Do not leave the device 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 wipe the face after removing the mask.
- To avoid injury to the nose mucosa, do not squeeze the nosepiece into the back of the nose.
- Do not block the slit between the cap and the inhalation air inlet.
- Make sure that the vaporizer head is correctly installed before use.
- Do not use a damaged nebulizer kit, mouthpiece or nosepiece.
- While using this device, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields is within 30cm. This may result in degradation of performance of the device.

(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 approved by OMRON HEALTHCARE will void the user warranty.
- Do not pull the power cord 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 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.
- Using the device longer than the standard operating time for which it was designed may result in accidents such as fire or injury due to deterioration over time.

Keep these instructions for future reference.

Technical data

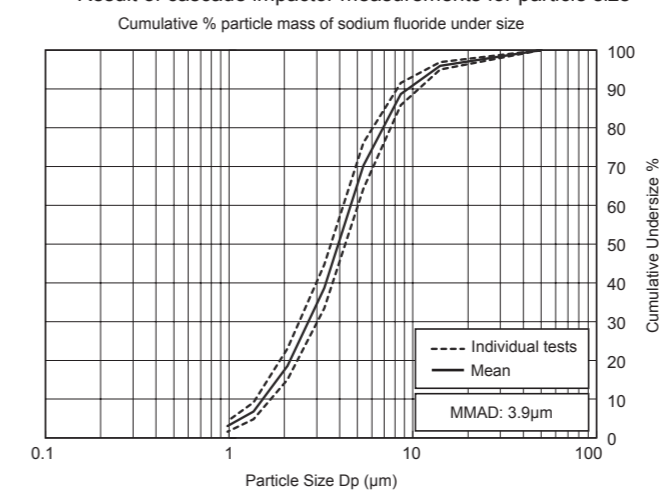
Product Category:	Nebulizers
Product Description:	Compressor Nebulizer
Model:	NE-C101
Rating:	230V~ 50Hz
Power Consumption:	150VA
Current Fuse:	T1.6AL250V
Operating Mode:	Continuous Use
Operating Temperature/ Humidity/Air Pressure:	+5°C to +40°C / 15% to 85%RH (non-condensing) 700 to 1060hPa
Storage and Transport Temperature/Humidity:	-20°C to +60°C / 5% to 95%RH (non-condensing)
Weight:	Approx. 1.05kg (compressor only)
Dimensions:	Approx. 145 (W) × 124 (H) × 182 (D) mm (compressor only)
Contents:	Compressor, Nebulizer Kit, Air Tube (PVC, 100cm), Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), 2 pcs Spare Air Filters, Instruction Manual, Quick Start Guide.
Classification:	Class II (Protection against electric shock), Type BF (Applied part); Mouthpiece, Nosepiece, Mask IP21 (Ingress Protection)

CE 0197

Technical data for the NE-C101 Compressor:

Particle Size:	**MMAD Approx. 3.90µm MMAD = Mass Median Aerodynamic Diameter
Medication Tank Capacity:	12ml maximum
Appropriate Medication Quantities:	2ml minimum - 12ml maximum
Noise level (at 1m distance):	*Less than 63dB
Nebulization Rate:	*Approx. 0.3ml/min (by weight loss)
Aerosol Output:	0.259ml (2ml, 1%NaF)
Aerosol Output Rate:	0.05ml/min (2ml, 1%NaF)

Result of cascade impactor measurements for particle size**



* Measured by OMRON HEALTHCARE Co., Ltd.

** Measured values reflect internal data obtained by NEXT GENERATION IMPACTOR (NGI), according to EN13544-1:2007 + A1:2009 and ISO27427:2013.

Notes:

- Subject to technical modification without prior notice.
- This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co., Ltd., Japan.
- The device may not work if the temperature and voltage conditions are different to those defined in the specifications.
- Ensure that this device has acclimated to room temperature before nebulizing the medication. Nebulizing the medication after an extreme temperature change could lead to less nebulization. OMRON recommends waiting for approximately 2 hours for the device to warm up or cool down when the device is used at an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information of operating and storage/transport temperature, refer to Technical data.
- The device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN13544-1:2007+A1:2009, Respiratory therapy equipment - Part1: Nebulizing systems and their components.
- Performance may vary with medication such as suspensions or high viscosity. See medication supplier's data sheet for further details.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. The device is protected against solid foreign objects of 12.5mm diameter and greater such as finger and against vertically falling water drops which may cause issues during a normal operation.

Symbols description	
	Need for the user to consult the instructions for use
	Applied part - Type BF Degree of protection against electric shock (leakage current)
	Class II Protection against electric shock
IPXX	Ingress protection degree provided by IEC 60529
	CE Marking
	Serial number
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Power OFF
	Power ON
	Alternating current
Product production date is integrated in the Serial number, which placed on the product and/or sales package: the first 4 digits mean year of production, the next 2 digits mean month of production.	

**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.

Optional Medical Accessories

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

Product description	Model
Nebulizer Kit	NEB-NK-11AP
Nebulizer Kit & Adult Mask & Air Tube Set	NEB-NSET4-11AP
Nebulizer Kit & Child Mask & Air Tube Set	NEB-NSET5-11AP
Adult Mask (PVC)	NEB-MSLP-AP
Child Mask (PVC)	NEB-MSMP-AP
Mouthpiece	NEB-MP-AP
Nosepiece	NEB-NP-AP
Air Tube (PVC, 100cm)	NEB-TP-L10AP

Other Optional/Replacement Parts

Product description	Model
Air Filters x 5	NEB-AFR-30AP

How to use

⚠ Warning:

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

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

1. Make sure that the power switch is in the off (O) position.

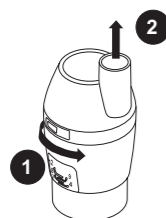
2. Plug the power plug into a power outlet.

Note:

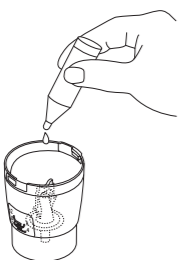
Do not place the device in a location where it is difficult to disconnect the power cord.

3. Remove the inhalation top from the medication tank.

- 1) Rotate the inhalation top anti-clockwise.
- 2) Lift the inhalation top out of the medication tank.



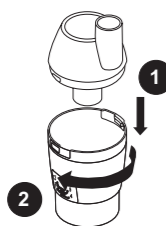
4. Add the correct amount of prescribed medication to the medication tank.



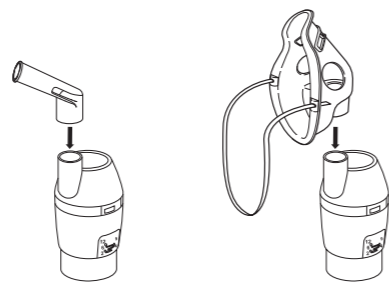
5. Make sure that the vaporizer head is placed in the medication tank.

6. Put the inhalation top back onto the medication tank.

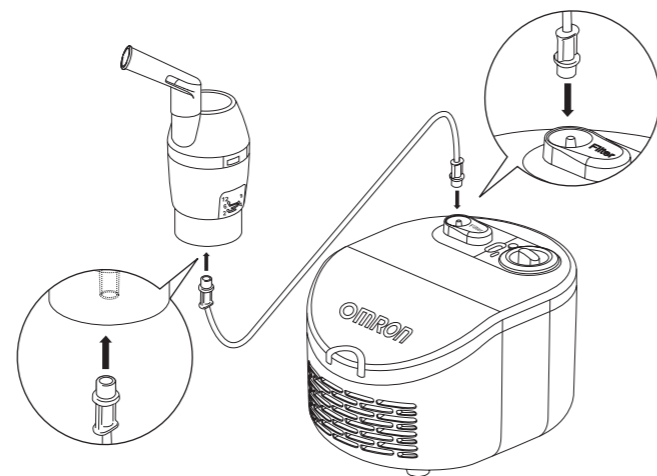
- 1) Lower the inhalation top on the medication tank.
- 2) Rotate the inhalation top clockwise.



7. Attach the mask, mouthpiece or nosepiece to the nebulizer kit tightly.



8. Attach the air tube. Twist the air tube plug slightly and push it firmly into the air tube connector.



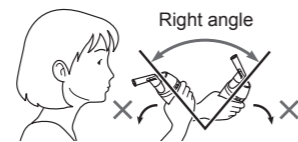
9. Hold the nebulizer kit as indicated below.

Follow the instructions of your doctor or respiratory therapist.



⚠ Caution:

Do not tilt the nebulizer kit at an angle of greater than 30 degrees in all directions. Medication may flow into the mouth or it may result in not nebulizing effectively.



10. Turn the power switch to the on (I) position. As the compressor starts, nebulization begins and aerosol is generated.

Inhale the medication.

11. When treatment is complete, turn the power off and unplug the compressor from the power outlet.

Cleaning and disinfecting

⚠ Caution: Handling the Vaporizer Head

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

Cleaning

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

■ Washable parts

• Nebulizer Kit, Mask (PVC), Mouthpiece, Nosepiece

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.

Disinfecting

Disinfect the parts once a week. If the parts are heavily stained, replace them with new ones.

To select a method for disinfection, refer to the table below.

O: applicable X: not applicable

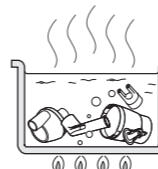
Disinfecting method	Parts	Mouthpiece	Nosepiece	Nebulizer Kit	Adult Mask (PVC) Child Mask (PVC)	Air Tube (PVC, 100cm)	Air Filter
	Materials	PP	PP	PP	Mask: PVC (Phthalate free) Band: Rubber**	PVC (Phthalate free)	Polyester
A	Alcohol	O	O	O	O**	X	X
	Disinfecting ethanol	O	O	O	O**	X	X
	Sodium hypochlorite	O	O	O	O**	X	X
	Milton* (0.1%, 15min.)	O	O	O	O**	X	X
	Quaternary ammonium	O	O	O	O**	X	X
	Osvan* (0.1%, 10min.)	O	O	O	O**	X	X
	Chlorhexidine	O	O	O	O**	X	X
B	Hibitane* (0.5%, 30min.)	O	O	O	O**	X	X
	Amphoteric Surfactant	O	O	O	O**	X	X
	Tego 51* (0.2%, 15min.)	O	O	O	O**	X	X
B	Boiling	O	O	O	X	X	X

* 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 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.



Removing condensation from the air tube

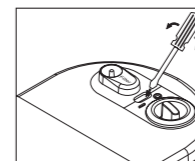
If there is moisture or liquid remaining in the air tube, be sure to follow the procedure below to remove any moisture from within the air tube.

- 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.

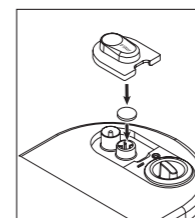
Changing the air filter

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

1. Remove the air filter cover using a flat screwdriver as shown on the right.



2. Change the air filter. Remove the old air filter and insert the new air filter.



3. Put the air filter cover back in place. Make sure it is attached properly.

Notes:

- Use only OMRON air filters designed for this device. Do not operate without a filter.
- Do not wash or clean the filter. If the air filter becomes wet, replace it. Damp air filters can cause blockages.
- There is no front or back orientation for the air filters.
- Check that air filters are clean and free of dust before inserting them.

Troubleshooting

In case of any of the below problems occur during use, first check that no other electrical device is within 30cm.

If the problem persists, please refer to the table below.

Problem	Cause	Remedy
Nothing happens when the power switch is turned on.	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 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 30 degrees.
	Is the air tube connected correctly?	Make sure that the air tube is correctly connected to the compressor and nebulizer kit.
The compressor is abnormally loud.	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 very hot.	Is the air filter cover attached correctly?	Attach the air filter cover correctly.
	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.

Note: If the suggested remedy does not solve the problem, do not try to repair the device - the device are not user serviceable. Please contact an authorized OMRON representative for assistance.

Important information regarding Electro Magnetic Compatibility (EMC)

NE-C101 manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at <http://www.omronhealthcare-ap.com/emc-information>. Refer to the EMC information for NE-C101 on the web site.