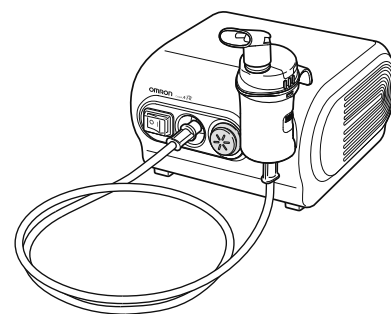
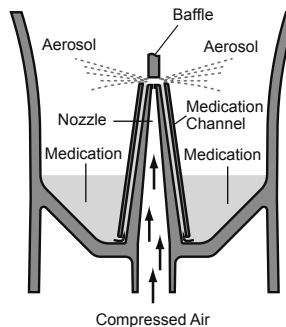


Thank you for purchasing the OMRON COMP AIR. This product was developed in conjunction with respiratory therapists for the successful treatment of asthma, chronic bronchitis, allergies and other respiratory disorders. This is a medical device. Operate the device only as instructed by your doctor and/or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



COMP AIR

Compressor Nebulizer Model NE-C28P

Instruction Manual

EN

| | |
|--|--|
| | Manufacturer OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002 JAPAN |
| | EU-representative OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com |
| | Production facility OMRON (DALIAN) CO., LTD. Dalian, CHINA |
| | Subsidiary OMRON HEALTHCARE UK LTD. Opal Drive, Fox Milne, Milton Keynes, MK15 0DG, U.K. OMRON MEDIZINTECHNIK HANDELSGESELLSCHAFT mbH John-Deere-Str. 81a, 68163 Mannheim, GERMANY www.omron-medizintechnik.de OMRON SANTÉ FRANCE SAS 14, rue de Lisbonne, 93561 Rosny-sous-Bois Cedex, FRANCE |

Made in China

All for Healthcare

IM-NE-C28P-E-EN-03-01/2013
1675597-9A

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-C28P 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.

| | |
|------------------------|---------|
| Compressor (Main unit) | 5 years |
| Nebulizer Kit | 1 year |
| Mouthpiece | 1 year |
| Nosepiece | 1 year |
| Air Tube (PVC, 200cm) | 1 year |
| Air Filter | 60 days |
| Mask (PVC)/(SEBS) | 1 year |

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.

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 feel anything unusual during use, stop using the device immediately and consult your doctor.
- Do not use only water in the nebulizer for inhaling purposes.
- Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- Do not store the air tube while there is moisture or medication remaining inside.
- Do not use or store the device where it may be exposed to noxious fumes or volatile substances.
- Do not use the device where it may be exposed to flammable gas.
- Do not cover the compressor with a blanket, towel, or any other type of cover during use.
- Always dispose of any remaining medication after use, and use fresh medication each time.
- Do not use in anaesthetic or ventilator breathing circuits.
- Do not block the ventilation slots. Never place the device where the ventilation slots may be obstructed during operation.
- Store the parts in a clean location for avoiding infection.

(Risk of electrical shock)

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

(Cleaning and disinfecting)

- Observe the rules below when cleaning or disinfecting parts. Failure to observe these rules may result in damage, inefficient nebulization or infection. For the instructions, refer to "Cleaning and disinfecting" section.
- Clean and disinfect the nebulizer kit, mask, mouthpiece or nosepiece before using them when as follows:
 - the first time after purchase
 - if the device has not been used for a long period of time
 - if more than one person uses the same device
- Be sure to wash or wipe the parts after use, and ensure that they are thoroughly disinfected and dried, and stored in a clean location.
- Do not leave the cleaning solution in the parts.

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

(Usage)

- Provide close supervision when this device is used by, on, or near children or invalids.
- Make sure that the parts are attached correctly.
- Make sure that the air filter is correctly attached.
- Make sure that the air filter is clean. If the air filter has been used for more than 60 days, replace it with a new one.
- Do not tilt the nebulizer kit at an angle of greater than 45 degrees in all directions or shake it while in use.
- Do not use or store the device while the air tube is creased.
- Use only original nebulizing parts, air tube, air filter and air filter cover.
- Do not add more than 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 the device on the floor.
- Do not distort the vaporiser head, or jab the nozzle of the medication tank with a pin or any sharp object.
- Do not insert fingers or objects inside the compressor.
- Do not disassemble or attempt to repair the compressor or power cord.
- Do not leave the device or its parts in extreme hot or cold temperature, or under direct sunlight.
- Do not block the air filter cover.
- Do not use the device while sleeping or if drowsy.
- Approved for human use only.
- The compressor may become hot during operation.
- Do not touch the compressor for other than necessary operation such as turning off the power while nebulizing.
- To avoid the medication residue on the face, be sure to 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 vaporiser head is correctly installed before use.
- Do not use a damaged nebulizer kit, mouthpiece or nosepiece.

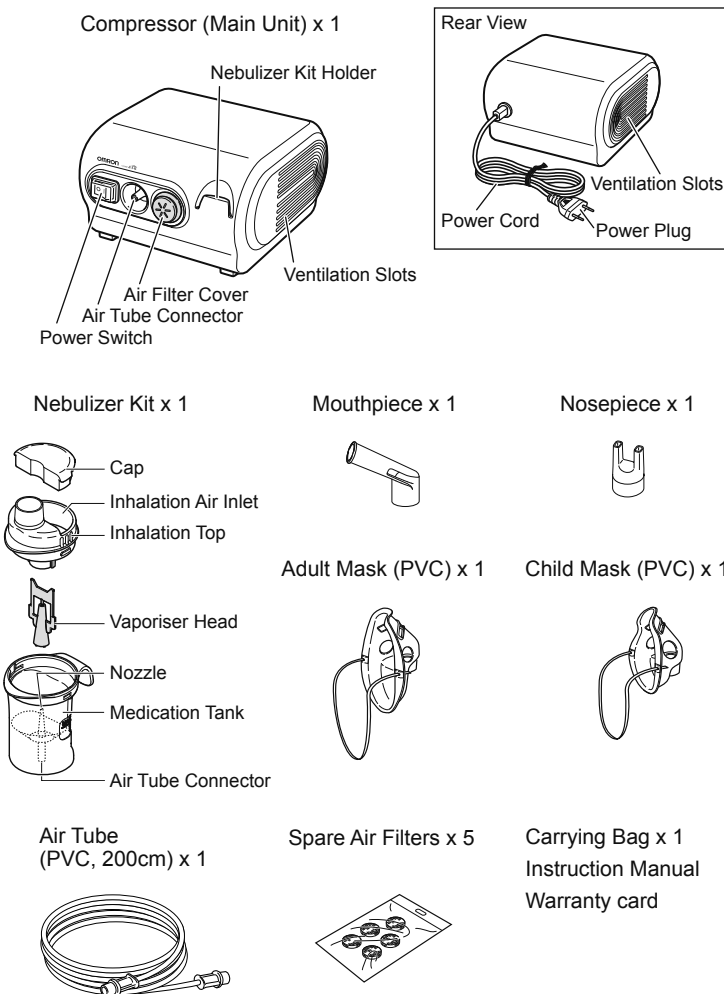
(Risk of electrical shock)

- Always unplug the device from the power outlet after use and before cleaning.
- Plug the device into the appropriate voltage outlet. Do not overload power outlets or use extension cords.
- Do not misuse the power cord.
- Do not wind the power cord around the compressor.
- Changes or modifications not approved by OMRON HEALTHCARE will void the user warranty.

(Cleaning and disinfecting)

- Observe the rules below when cleaning or disinfecting parts. Failure to observe these rules may result in damage, inefficient nebulization or infection. For the instructions, refer to "Cleaning and disinfecting" section.
- Do not use a microwave oven, dish dryer or hair dryer to dry the device or the parts.
- Do not use an autoclave, EOG gas sterilizer or low temperature plasma sterilizer.
- When disinfecting parts by boiling, make sure that the container does not boil dry. Otherwise it may also result in fire.

Know your unit



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.

Keep these instructions for future reference.

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 EN60601-1-2:2007 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.

This medical device manufactured by OMRON HEALTHCARE conforms to this EN60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- 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.

Further documentation in accordance with EN60601-1-2:2007 is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual.

Documentation is also available at www.omron-healthcare.com.



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 wastes for disposal.

Optional Medical Accessories

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

| Name | Model | Order No. |
|--|---------------|-----------|
| V.V.T. Nebulizer Kit N-01 & Mouthpiece Set | NEB-NSET3-81E | 9515573-6 |
| Adult Mask (PVC) | NEB-MSLP-E | 9956275-1 |
| Child Mask (PVC) | NEB-MSMP-E | 9956276-0 |
| Adult Mask (SEBS) | NEB-MSLS-E | 9956312-0 |
| Child Mask (SEBS) Set | NEB-MSSS-E | 9956281-6 |
| Mouthpiece | NEB-MP-E | 9956273-5 |
| Nosepiece | NEB-NP-E | 9956274-3 |
| Air Tube (PVC, 200cm) | NEB-TP-L20E | 9520606-3 |
| Air Tube (Silicone, 100cm) | NEB-TSC-L10E | 9956269-7 |


Other Optional/Replacement Parts

| Name | Model | Order No. |
|-----------------|-------------|-----------|
| Air Filters x 5 | NEB-AFR-28E | 9956271-9 |

How to use

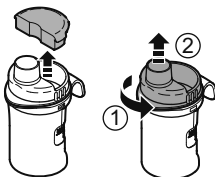
Warning:

- 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 () position.

2. Plug the power plug into a power outlet.

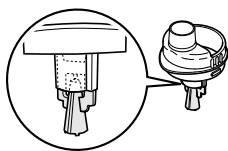
3. Remove the cap and the inhalation top from the medication tank.



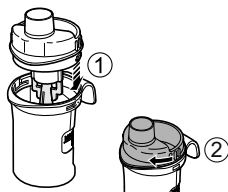
4. Add the correct amount of prescribed medication to the medication tank.



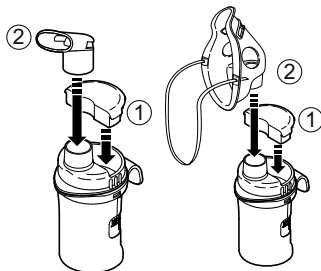
5. Make sure that the vaporiser head is securely attached to the inhalation top.



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



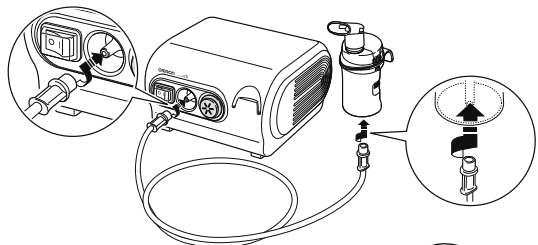
7. Attach the cap and mask, mouthpiece or nosepiece to the nebulizer kit tightly.



Note:

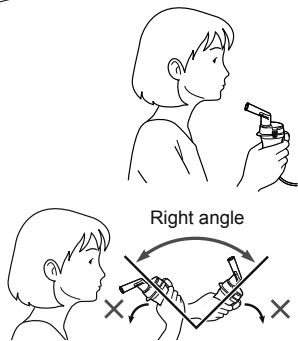
It is not necessary to attach the cap when nebulizing with Adult mask. If the amount of aerosol is too great, attach the cap.

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 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.

10. Press the power switch to the on () 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 daily disinfecting

Cleaning

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

Washable parts

• Nebulizer Kit, Mask (PVC)/(SEBS), Mouthpiece, Nosepiece, 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.

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

Always disinfect the parts after the last treatment of the day. If the parts are heavily stained, replace them with new ones.

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

○: applicable X: not applicable

| Disinfecting method | Parts | Mouthpiece | Nosepiece | Nebulizer Kit | Air Tube (Silicone, 100cm) (optional) | Adult Mask (SEBS) (optional) | Child Mask (SEBS) (optional) | Adult Mask (PVC) Child Mask (PVC) | Air Tube (PVC, 200cm) | Air Filter |
|---------------------|-----------------------|------------|-----------|-------------------------|---------------------------------------|---|---|-----------------------------------|-----------------------|------------|
| | | PP | PP | PP (Vaporiser Head: PC) | Tube: Silicone Connector: PP | Mask: SEBS Band: Rubber (non-latex) Adapter: PP | Mask: PVC (Phthalate free) Band: Rubber (non-latex) | PVC (Phthalate free) | Polyester | |
| A | Alcohol | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Disinfecting ethanol | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Sodium hypochlorite | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Milton* | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Quaternary ammonium | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Osvan* | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Chlorhexidine | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Hibitane* | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| B | Amphoteric Surfactant | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Tego* | ○ | ○ | ○ | ○ | ○ | ○ | ○ | X | X |
| | Boiling | ○ | ○ | ○ | ○ | ○ | ○ | X | X | X |

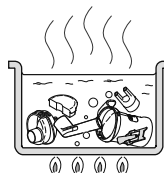
* an example of commercially available disinfectant.

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.



Caution: Handling the Vaporiser Head

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

Removing condensation from the air tube

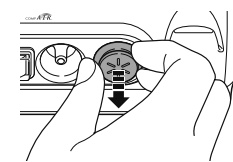
If there is moisture or liquid remaining in the air tube, be sure to follow the procedure below to remove any moisture from within the air tube.

- Make sure that the air tube is connected to the air connector on the compressor.
- Remove the air tube from the nebulizer kit.
- 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.

- Pull the air filter cover off the compressor.



- Change the air filter. Remove the old air filter with a sharp object and insert the new air filter.



- 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







Check the following if the device should fail during operation.

| Problem | Cause | Remedy |
|---|---|--|
| Nothing happens when the power switch is pressed. | 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 vaporiser head missing or not assembled correctly? | Attach the vaporiser head correctly. |
| | Is the nebulizer kit assembled correctly? | Assemble the nebulizer kit correctly. |
| | Is the nozzle blocked? | Make sure that the nozzle is free of blockages. |
| | Is the nebulizer kit tilted at a sharp angle? | Make sure that the nebulizer kit is not 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 compressor is abnormally loud. | Is the air filter cover attached correctly? | Attach the air filter cover correctly. |
| The compressor is very hot. | Is the compressor covered? | Do not cover the compressor with any type of cover during use. |
| | Are the ventilation slots blocked? | Do not block the ventilation slots. |

Note: If the suggested remedy does not solve the problem, do not try to repair the device - no parts of the device are user serviceable. Return the device to an authorized OMRON retail outlet or distributor.

Technical data

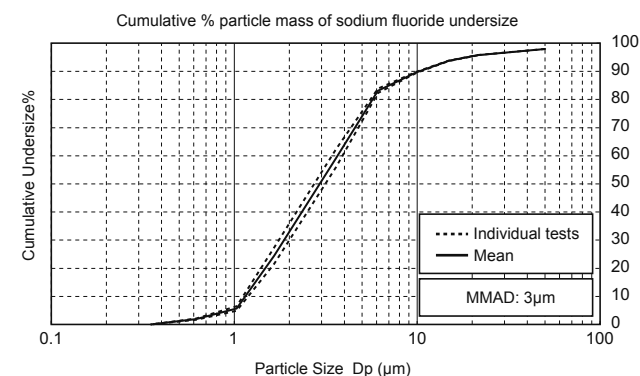
| | |
|---|--|
| Name: | COMP AIR |
| Model: | NE-C28P (NE-C28P-E) |
| Type: | Compressor Nebulizer |
| Rating: | 220-240V, 50/60Hz |
| Power Consumption: | 192VA |
| Operating Temperature/ Humidity: | +10°C to +40°C / 30% to 85%RH |
| Storage and Transport Temperature/Humidity/ Air Pressure: | -20°C to +60°C / 10% to 95%RH / 700 - 1060hPa |
| Weight: | Approx. 1.9kg (compressor only) |
| Dimensions: | Approx. 170 (W) × 103 (H) × 182 (D) mm |
| Contents: | Compressor, Nebulizer Kit, Air Tube (PVC, 200cm), Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), 5 pcs Spare Air Filters, Carrying Bag, Instruction Manual, Warranty Card. |
| Classification: | Class II equipment, Type B applied part |

| | | | | | |
|---|----------------------|---|-----------------------|---|---------------------------------------|
|  | = Class II equipment |  | = Type B applied part |  | Read the instruction manual carefully |
|  | = Power off |  | = Power on |  | CE 0197 |

Technical data for the OMRON NE-C28P Compressor with the V.V.T. Nebulizer Kit N-01:

| | |
|------------------------------------|---|
| Particle Size: | **MMAD Approx. 3µm MMAD = Mass Median Aerodynamic Diameter |
| Medication Tank Capacity: | 7ml maximum |
| Appropriate Medication Quantities: | 2ml minimum - 7ml maximum |
| Sound: | *Noise level (at 1 m distance) 60dB |
| Nebulization Rate: | *Approx. 0.5ml/min (by weight loss) |
| Aerosol Output: | **0.4ml (2ml, 1%NaF) |
| Aerosol Output Rate: | **0.09ml/min (2ml, 1%NaF) |

Result of cascade impactor measurements for particle 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+A1:2009.

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.
- 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 drugs such as suspensions or high viscosity. See drug supplier's data sheet for further details.
- See website of OMRON HEALTHCARE EUROPE to update technical information. URL: www.omron-healthcare.com