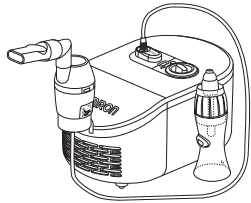


OMRON



Compressor Nebulizer C102 Total (NE-C102-E)

Instruction Manual

All for Healthcare

IM-NE-C102-E-01-12/2017
3A3770 rev.00

Intended use

Medical Purpose

This product is intended to be used for inhaling medication for respiratory disorders. The nasal shower is a nasal irrigation system for rinsing the nasal and rhino-pharyngeal cavities.

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 C102 Total and the content of this instruction manual.

Intended Patients

Persons who suffer from respiratory disorders and require inhalation of medications or who require rinsing of their nasal and rhino-pharyngeal cavities.

Environment

This product is intended for use in a general household.

Durable period

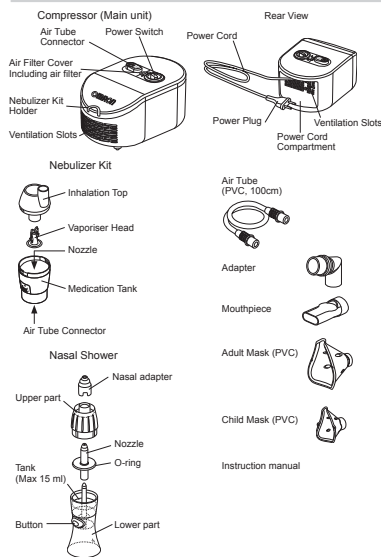
Durable periods are as follows, provided the product is used to nebulize 3 times a day for 10 minutes each time at room temperature (23°C).

| | |
|------------------------|-----------------|
| Compressor (Main unit) | 5 years |
| Air Tube | 1 year |
| Nebulizer Kit | 1 year |
| Mouthpiece | 1 year |
| Child Mask | 1 year |
| Adult Mask | 1 year |
| Adapter | 1 year |
| Nasal Shower | 1 year |
| Air Filter | 70 applications |

Durable period may vary depending on usage environment.

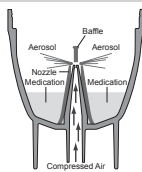
Frequent usage of the product may shorten the durable period.

Know your unit



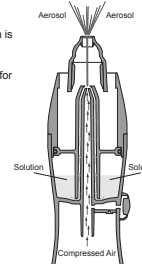
How the nebulizer kit works

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.



How the Nasal Shower works

The solution that is pumped up through the channel is mixed with compressed air which is generated by a compressor pump. The compressed air mixed with solution is turned into fine particles ready for irrigation for the nasal and rhino-pharyngeal cavities.



Important safety instructions (Read before use)

Warning:

1. Use the device only as nebulizer for therapeutic purposes. Any other use is improper and may be dangerous. The manufacturer is not liable for improper uses.
2. Do not use in anaesthetic or ventilator breathing circuits.
3. Always disconnect the power plug after use. The compressor could get hot and there is a possible risk of a burn if touched.
4. Do not to cover the ventilation slots during use. The compressor could get hot and there is a possible risk of a burn if touched.
5. The compressor and power plug are not waterproof. Do not spill water or other liquids on these parts. If liquid does spill on these parts, immediately unplug the power plug and wipe off the liquid.
6. Do not attempt to repair the device. See Troubleshooting section.
7. Keep the device out of reach of unsupervised infants and children. The device contains small pieces that can be swallowed.
8. Provide close supervision when this device is used by, on, or near children or persons with limited capabilities.
9. For type, dose, and regimen of medication follow the instructions of your doctor or respiratory specialist.
10. This product should not be used on patients, who are unconscious or are not breathing spontaneously.
11. After finishing the treatment disconnect the air tube from the nebulizer kit and from the compressor.
12. In view of their length, the power cord and air tube could constitute a strangulation hazard.
13. Be sure to use the compressor at a place where the power plug is easily accessible during treatment.
14. If you experience any allergic reactions or other difficulties during use, stop using the device immediately and consult your doctor or respiratory specialist.
15. While using this device, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields is within 30 cm. This may result in degradation of performance of the device.
16. Do not use Nasal Shower for any other purpose except for its intended use as a nasal irrigation device.

How to use

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 from the medication tank.
4. Add the correct amount of prescribed medication into the medication tank.
5. Verify the presence of the vapouriser head inside 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 adapter, and the Mask or mouthpiece 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 on the right. Follow the instructions of your doctor or respiratory specialist.

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 ineffective nebulization.

10. Turn the power switch to the on (I) position. As the compressor starts, nebulization begins and aerosol is generated. Gently inhale the medication. Exhale through the nebulizer kit.
11. When treatment is completed, turn the power off and unplug the compressor from the power outlet. Wind the power cord up and store it in the compartment at the back of the device.

Preparation of the Nasal Shower

1. In order to add the solution to the nasal shower tank, lift the upper part out of the tank as shown on the figure. Remove the upper part.
2. Pour the solution in the tank (max 15 ml).
3. Close the nasal shower by placing back the upper part.
4. Connect one end of the air hose to the nasal shower and the other end to the compressor. Turn on the compressor to begin the treatment.

Operation of the Nasal Shower

Operate the nasal shower by pressing the button and release it before/during exhaling. During treatment, hold the other nostril, to which the nasal shower is not applied, closed with one finger.

In the case of children or patients with limited capabilities, apply to the two nostrils in alternation, switching every 10-20 seconds. Keep a handkerchief ready to dry the nostrils if mucous overflows from the trap in the upper part of the nasal shower.

When the mist starts disappearing from the nasal shower the treatment is done. After use, dispose of any solution from both upper part and tank, disassemble the Nasal Shower to the 4 parts as indicated in section "Know your unit" and clean the parts according to the instructions below.

Note: NEVER INHALE WHILE IN A HORIZONTAL POSITION. NEVER TILT THE NASAL SHOWER TO MORE THAN 60°.

Cleaning and daily disinfecting

Carefully wash your hands before cleaning and disinfecting the nebulizer parts. Clean the parts after each use to remove residual medication. This will prevent inefficient nebulization and reduce risk of infection.

- **Cleaning the Nebulizer Kit, Nasal shower, Masks*, Mouthpiece and Adapter:** Fully disassemble the Nebulizer Kit and the Nasal Shower. Wash them in warm water and mild, neutral detergent. Rinse them thoroughly with clean hot tap water, gently tap to remove excess water and allow to air dry in a clean place. It is advisable to replace the Nebulizer Kit and Nasal Shower after some 100 to 120 treatments or after about 20 boiling cycles.

- **Cleaning the Compressor and Air Tube:** Firstly, make sure that the power plug is unplugged from the power outlet. Wipe clean with a soft cloth moistened with water or mild, neutral detergent.

- **Disinfecting the Nebulizer Kit, Nasal shower, Masks*, Mouthpiece and Adapter:** Always disinfect the parts before using the product for the first time and after the product has not been used for an extended period of time as well as after the last treatment of the day. If the parts are heavily stained, replace them with new ones. The Nebulizer Kit, Nasal shower, Masks*, Mouthpiece and Adapter can be disinfected by using a chemical disinfectant such as ethanol, sodium hypochlorite (Milton), Quaternary ammonium (Osvan), Chlorhexidine (Hibitane) and Amphoteric Surfactant (Tego), following product instructions and rinsing off with clean warm water. Leave to air-dry.
Note: Never clean with benzene, thinner or a flammable chemical. *The (non-latex) elastic bands cannot be disinfected. Remove them when disinfecting the masks.

- **Boiling:** The Nebulizer Kit, Nasal shower, Mouthpiece and Adapter can also be disinfected by boiling between 15 to 20 minutes in plenty of water. After boiling, carefully remove the parts, shake off excess water and allow to air-dry in a clean environment.
Note: Do not boil the Mask and the Air Tube.

Replacing the Air Filter:

If the air filter has changed color, or has been used for more than 70 applications, replace it with a new one. To purchase the filters – see "Other Optional/Replacement Parts" paragraph. Remove the air filter cover using a flat screwdriver as shown in figure; remove the filter and fit the new filter as shown. Put the air filter cover back in place.

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



Troubleshooting

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

The device does not switch on

- Check that the power plug is properly fitted to the power outlet.
- Make sure the power switch is in the on position (I).

The device switches on but does not nebulize

- Make sure the vaporizer head is fitted in the nebulizer kit or if you are using the nasal shower, check that the nasal shower is assembled correctly.
- Make sure the air tube is not squashed or crooked.
- Check the air filter for blockage and dirt. Replace if necessary.
- Check that sufficient amount of medication has been put into the nebulizer kit.









The device suddenly stops working during operation

- The thermal cut-out has shut the device down for one of the following reasons:
 - the device was working in an environment with temperatures higher than 40°C.
 - the ventilation slots were covered.

Do not attempt to repair the device. Do not open and/or tamper with the device. No parts of the device are user serviceable. Return the device to an authorized OMRON retail outlet or distributor.

Technical data

| | |
|--|--|
| Product Category: | Aerosoltherapy Equipment |
| Product Description: | Compressor Nebulizer |
| Model (code): | C102 Total (NE-C102-E) |
| Rating: | 230V ~50Hz, (fuse: T1.6AL250V) |
| Power Consumption: | 150VA |
| Operating Mode: | Continuous Use |
| Operating Temperature/Humidity/Air Pressure: | +5°C to +40°C / 15% to 85%RH / 700 to 1060 hPa |
| Storage and Transport Temperature/Humidity/Air Pressure: | -20°C to +60°C / 5% to 95%RH / 500 to 1060 hPa |
| Weight: | Approx. 1.1 kg (compressor only) |
| Dimensions: | Approx. 145 (W) × 124 (H) × 222 (D) mm |
| Classifications: | Type BF (Applied part): Mouthpiece, Masks and Nasal adaptor IP21 (Ingress Protection) |
| Contents: | Compressor, Nebulizer Kit, Nasal shower, Air Tube (PVC, 100 cm), Mouthpiece, Adapter, Adult Mask (PVC), Child Mask (PVC), Instruction Manual |

| | | | | | | | |
|---|----------------------|---|------------------------------------|---|-----------------------------|---|-------------|
|  | = Class II equipment |  | = Type BF applied part |  | = IP21 = Ingress Protection |  | = Power off |
|  | = Serial number |  | = Consult the instructions for use |  | = Alternating current |  | = Power on |

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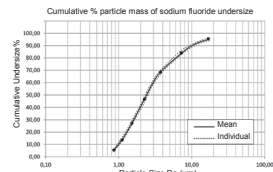
General Notes:

- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. The compressor is protected against solid foreign objects of 12 mm diameter and greater such as a finger, and against vertically falling water drops which may cause issues during a normal operation.
- Subject to technical modification without prior notice.
- 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.

Nebulizer Kit:

| | |
|--------------------------------------|--|
| Appropriate Medication Quantities: | 2 ml minimum - 12 ml maximum |
| Residual volume of medication: | Approx. 0.7 ml |
| Sound: Noise level (at 1 m distance) | Approx 57 dB |
| Particle Size (MMAD): | *Approx. 2.6 µm MMAD = Mass Median Aerodynamic Diameter |
| Nebulization Rate (by weight loss): | **Approx. 0.35 ml/min (NaCl 0.9%) |
| Aerosol Output (2 ml, 1% NaF): | ***Approx. 0.25 ml |
| Aerosol Output Rate (2 ml, 1% NaF): | ***Approx. 0.07 ml/min |

Nebulizer Kit: Result of cascade impactor measurements for particle size*



Notes:

- Performance may vary with drugs such as suspensions or high viscosity. See drug supplier's data sheet for further details
- Measured values reflect internal data obtained by NEXT GENERATION IMPACTOR (NGI), according to EN 13544-1:2007+A1:2009.
- *The Nebulization rate is measured with saline 0.9% solution at 23°C with 3 ml of medication. It can vary with medication and ambient conditions.
- **Measured by OMRON HEALTHCARE Co., LTD.

Nasal shower:

| | |
|-------------------------------------|--------------------------------|
| Appropriate Solution Quantities: | 3 ml minimum - 15 ml maximum |
| Particle Size: | 90% of particles > 10 µm |
| Nebulization Rate (by weight loss): | more than 5 ml/min (NaCl 0.9%) |

Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.

This product is guaranteed by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product is guaranteed by OMRON. During this period of guarantee OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts.

The guarantee does not cover any of the following:

- Transport costs and risks of transport.
- Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
- Periodic check-ups and maintenance.
- Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly guaranteed above.
- Costs arising due to non-acceptance of a claim (those will be charged for).
- Damages of any kind including personal caused accidentally or from misuse.

Should guarantee service be required please apply to the dealer whom the product was purchased from or an authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised retailer. If you have difficulties in finding OMRON customer services, contact us for information.

Repair or replacement under the guarantee does not give rise to any extension or renewal of the guarantee period.

The guarantee will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer. OMRON reserves the right to refuse the guarantee service if any unclear information has been given.

Optional Medical Accessories

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

| Product Description | Model |
|---|--------------|
| Nebulizer Accessory Set (Contents: Nebulizer Kit, Adapter, Mouthpiece, Nosepiece, Adult Mask (PVC), Child Mask (PVC), Air Tube, Air Filter) | NEB-ASKIT-11 |

Other Optional/Replacement Parts

| Product Description | Model |
|-------------------------------------|--------|
| Air Filter Set (Contents: 3 pieces) | 3AC408 |

Important information regarding Electro Magnetic Compatibility (EMC)
NE-C102-E manufactured by 3A HEALTH CARE S.r.l. conforms to EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual or at www.omron-healthcare.com. Refer to the EMC information for NE-C102-E on the website.



DISPOSAL PROCEDURE (Dir. 2012/19/EU-WEEE)

This product is not to be treated as regular household waste but must be returned to a collection point for recycling electric and electronic devices. Further information is available from your municipality, your municipality's waste disposal services, or the retailer where you purchased your product.

| | |
|---------------------|--|
| Manufacturer | 3A HEALTH CARE S.r.l. Via Marziale Cerutti, 90F/G 25017 Lonato del Garda (BS) Italy |
| Distributor | OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com |
| Subsidiaries | OMRON HEALTHCARE UK LTD. Opal Drive, Fox Milne, Milton Keynes, MK15 9DG, UK www.omron-healthcare.com OMRON MEDIZINTECHNIK HANDELSGESELLSCHAFT mbH Gottlieb-Daimler-Strasse 10, 68165 Mannheim, GERMANY www.omron-healthcare.com OMRON SANTÉ FRANCE SAS 14, rue de Lisbonne, 93561 Rosny-sous-Bois Cedex, FRANCE www.omron-healthcare.com |

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