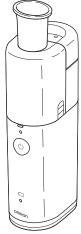
## **Instruction manual**



# MICRO Mix<sup>®</sup> Vibrating Mesh Nebulizer NE-U100

For single patient use only





All for Healthcare

EN ES

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### Introduction

Thank you for purchasing the Omron® MICROAir® NE-U100.

Omron Healthcare has moved forward in the development of electronic nebulizer technology with the introduction of the MICROAir NE-U100. Focusing on patient convenience and compliance as its goal, this device offers ultimate portability and a revolutionary vibrating mesh technology that provides a precise, powerful and effective treatment.

#### ■ Safety Instructions

This instruction manual provides you with important information about the OMRON NE-U100. To ensure the safe and proper use of this device, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact 1-800-634-4350 before attempting to use this device. For specific information about your own respiratory health, consult with your physician.

#### ■ Intended Use

The Omron NE-U100 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings.

It is not intended for use with Pentamidine.

#### ■ Receiving and Inspection

Remove this device from the packaging and inspect for damage. If this device is damaged, DO NOT USE and contact 1-800-634-4350.

### **■** Symbols Glossary

For symbol information, visit: OmronHealthcare.com/symbols-glossary

Please read the Important Safety Information in this instruction manual before using this device.

Please follow this instruction manual thoroughly for your safety.

Please keep for future reference. For specific information about your own device, CONSULT WITH YOUR PHYSICIAN.

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

- Failure to properly clean the MICROAir components will result in the risk of bacterial growth, serious illness from contamination, and compromised medication delivery.
- For type, dose, and regimen of medication, follow the instructions of your physician and/or licensed healthcare practitioner.
- DO NOT use Pentamidine with this device.
- If you experience any allergic reactions or other difficulties during use, stop using this device immediately and consult your physician.
- Keep this device out of the reach of unsupervised infants, toddlers and children. This device contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.
- ALWAYS dispose of any remaining medication after use. ALWAYS use fresh medication for each treatment.
- DO NOT use this device on persons who are unconscious or not breathing spontaneously.
- DO NOT use water only in the nebulizer for inhaling purposes.
- DO NOT touch the vibrating element while the power is on.
- DO NOT use this device where it may be exposed to flammable gas or vapors.
- DO NOT use or store this device in humid locations such as a bathroom.
- DO NOT leave this device or its parts in locations that are exposed to extreme temperature or humidity changes such as in a vehicle or in direct sunlight.
- DO NOT use in anesthetic or ventilator breathing circuits.
- Clean the parts of this device before using this device for the first time, after this device has not been used for an extended period of time and when parts are contaminated.
- Clean the parts of this device after each use.

- · Allow the parts to dry after cleaning before reassembling and store in a clean location so that this device will not become contaminated.
- DO NOT immerse the main unit (except the vibrating element and the area around the vibrating element) and the AC adapter in water or other liquid.
- DO NOT spill water or medication on the main unit and the AC adapter.
- DO NOT leave the cleaning solution in the parts. Rinse the parts with clean tap water after cleaning.
- Store this device and the components in a clean, safe location.

#### AC Adapter (optional accessory) Handling and Usage

- DO NOT use the AC adapter if this device or the AC adapter cable is damaged. If this device or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

⚠ Caution: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

- · This device is intended for human use only.
- To avoid the medication residue on the face, be sure to wipe the face after removing the mask.
- DO NOT get nebulized medication in your eves.
- DO NOT operate this device if the medication container is empty.
- · Use ONLY Omron authorized parts and accessories (Refer to section 6). Parts and accessories not approved for use with this device may damage the unit.
- DO NOT add more than 10ml of medication to the medication container.
- DO NOT subject the device to any strong shocks such as dropping the device on the floor.
- DO NOT cover the main unit with items such as a blanket or towel during use.
- DO NOT disassemble or attempt to repair the main unit or AC adapter.
- DO NOT push or poke at the mesh with items such as a cotton swab or pin.

- While using this device, make sure that no mobile phone or any other electrical devices that emit
  electromagnetic fields is within 12 inches (30cm). This may result in damage to the performance of
  the device.
- Inspect the main unit and the parts before each use to ensure that parts are not damaged, the
  device is assembled properly and it is operating normally.
- To prevent damage to the device, add the medication slowly. DO NOT allow the medication to overflow the Medication Port.
- To prevent damage to the device, make sure that the Mesh Cap is correctly in place. If the Mesh Cap is not properly closed, medication will leak out of the device.
- DO NOT operate the device at temperatures greater than +104°F (+40°C).
- Operate the device only as intended. DO NOT use the device for any other purpose.
- Changes or modifications not approved by Omron Healthcare will void the user warranty.
- Dry the parts by air drying only. DO NOT use any equipment to dry the device parts.
- To prevent damage to the device, DO NOT immerse the Main Unit in any liquid, DO NOT wash or rinse any of the parts under strong running water, and DO NOT touch the mesh with your hand or any object.
- To prevent damage to the device, DO NOT carry or leave the Medication Container filled with medication or distilled water.
- DO NOT use household bleach to clean the device or parts; doing so will cause rust and damage the Mesh Cap.
- To prevent damage to the device, DO NOT clean the Main Unit using abrasive cleaners or any type
  of chemical.
- · NEVER clean with benzene or thinner.
- 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 section 7.

#### AC Adapter (optional accessory) Handling and Usage

- Fully insert the AC adapter into the outlet. DO NOT use an extension cord.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the AC adapter cable.
- · When handling the AC adapter cable:
  - DO NOT damage it.
  - DO NOT break it.
  - DO NOT tamper with it.
  - DO NOT forcibly bend or pull it.
- DO NOT twist it.
- DO NOT use it if it is gathered in a bundle.
- DO NOT pinch it.
- DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- · Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this device.
- DO NOT put the AC Adapter in the Storage Case. The Storage Case is not intended to carry the AC Adapter.
- Use ONLY the AC adapter designed by Omron for this device (See page 31 for optional accessories). Use of any other AC adapter may damage the device.

#### **Battery Handling and Usage**

- Replace old batteries with new ones immediately. Replace both batteries at the same time.
- Remove the batteries if the unit will not be used for three months or more.
- DO NOT use different types of batteries together.
- DO NOT use new and used batteries together.
- DO NOT use lithium batteries.

### 1. Know Your Device

### 1.1 Contents

The following items are contained in the package:

Main Unit Cover



Main Unit



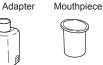
Medication Container



Mesh Cap



Mask Adapter



Batteries (2 "AA" alkaline batteries)



Child Mask (PVC)



Storage Case



Instruction Manual

### 1. Know Your Device

### 1.2 Name and Functions of the Parts

#### Mesh Cap

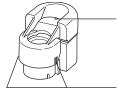
Contains metal alloy mesh for nebulization.



#### Mesh

Nebulized medication exits here through minute pores.

#### **Medication Container**



#### Air opening

Stabilizes nebulization.

#### Medication container lid release button

Medication container can be opened when the buttons on both sides are pressed.

#### Main Unit



The tip of this vibrating element oscillates at high frequency and pushes the medication through the pores of the mesh.

#### Power indicator

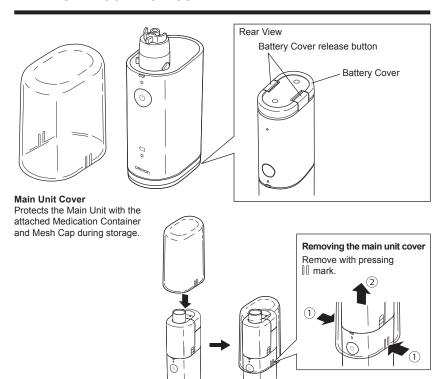
A green light turns on when the power is on.

### ON/OFF (心) button

#### **Battery Low Indicator**

An orange light blinks when the batteries are low.

### 1. Know Your Device



### 2.1 Before using the device for the first time

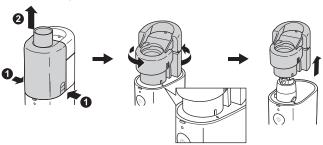
#### **♠**Warning:

- Failure to properly clean the MICROAir components will result in the risk of bacterial growth, serious illness from contamination, compromised medication delivery.
- Clean the parts of this device before using this device for the first time, after this device has not been used for an extended period of time and when parts are contaminated.

### Before first use: - Carefully read the instruction manual.

- Disassemble the parts and clean the mesh cap, medication container, mouthpiece, mask, mask adapter and vibrating element and its surrounding surface as shown below.
- Dry all parts completely before assembling the device.

### Disassembly



### 2.2 How to clean the device

#### · Mesh Cap

Wash the mesh cap in mild (neutral) detergent, then rinse off with distilled water. Remove excess water and allow to air dry in a clean place.

Some types of medications may remain on the mesh. Make sure to clean the medication from the mesh. Do not wash under running water.





· Medication Container, Mouthpiece, Mask and Mask Adapter

Wash the medication container, mouthpiece, mask and mask adapter in distilled water and mild (neutral) detergent.

Rinse the medication container, mouthpiece, mask and mask adapter thoroughly with distilled water and allow to air dry in a clean place.

Note: Remove the elastic band from the mask before cleaning.



 Vibrating element and its surrounding surface Wash under running tap water.

Note: To prevent liquid from entering the device, make sure that the battery cover is locked in place.



#### Main Unit

Clean the main unit by wiping it off with a (moistened) lint free cloth. Use a dry lint free cloth to wipe the main unit dry.

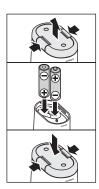
Never clean with benzene or thinner.



### 2.3 How to insert or replace the batteries

#### ⚠Caution:

- · DO NOT use new and used batteries together.
- · DO NOT use different types of batteries together.
- · DO NOT use lithium batteries.
- Replace old batteries with new ones immediately. Replace both batteries at the same time.
- Remove the batteries if the unit will not be used for three months or more.
- Remove the battery cover on bottom side by pressing on the release buttons on both sides
- Insert the batteries according to the battery polarity indicated inside the battery compartment.
- Replace battery cover by pressing buttons on both sides of the battery cover.

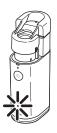


#### Battery life and battery replacement

The unit can operate with alkaline batteries or with nickel-metal-hydride (NiMH) rechargeable batteries. Depending on the capacity and condition of the batteries, the unit can operate up to 4 hours on a set of alkaline batteries.

#### Battery Low Indicator (orange light)

Flashes	The batteries are low. Replace both batteries with new ones.
Turns on	The batteries are depleted. The device will not nebulize. Immediately replace both batteries with new ones.



- Notes: The battery low indicator will turn off if no button is pressed for 10 seconds or if you turn off the device.
  - Batteries should be treated as chemical waste: disposal should be done at your retail store or at appropriate collection locations.

### 2.4 Using the AC adapter (Optional)

#### **♠**Warning:

- DO NOT use the AC adapter if this device or the AC adapter cable is damaged. If this device or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

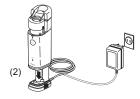
#### A Caution:

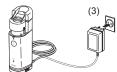
- Fully insert the AC adapter onto the outlet. DO NOT use an extension cord.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the AC adapter cable.
- · When handling the AC adapter cable:
  - DO NOT damage it.
  - DO NOT break it.
  - DO NOT tamper with it.
  - DO NOT forcibly bend or pull it. DO NOT twist it.
- DO NOT use it if it is gathered in a bundle.
- DO NOT pinch it.
- DO NOT place it under heavy objects.
- · Wipe any dust off of the AC adapter.
- · Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this device.
- DO NOT put the AC adapter in the Storage Case. The Storage Case is not intended to carry the AC adapter.
- Use ONLY the AC adapter designed by Omron from this device (See page 31 for optional accessories). Use of any other AC adapter may damage the device.

#### To connect the AC adapter to the main unit

- Remove the battery cover and take out the batteries (see page 13).
- (2) Place the main unit on the AC adapter connection stand as shown in the illustration on the right. Note: It will click and lock to the stand.
- (3) Insert the AC adapter power plug into an outlet.

Note: Do not place the device in a location where it is difficult to disconnect the AC adapter.

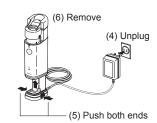




Connection is completed.

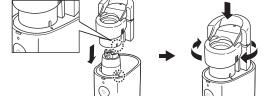
#### To remove the AC adapter from the main unit

- (4) Disconnect the AC adapter power plug from the outlet.
- (5) Push on both sides of the connection stand to unlock from the main unit.
- (6) Remove the main unit.

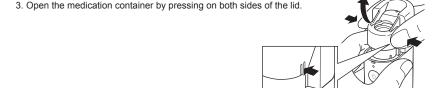


### 2.5 How to assemble the device and fill the medication container

- 1. Insert batteries or connect the optional AC adapter to the main unit, see page 13.
- Align the mark on the medication container with the mark on the main unit. Push down and rotate the medication container clockwise.



Note: Do not assemble the medication container to the main unit when the mesh cap is installed.



Fill the medication container as illustrated. The maximum capacity is 10 ml.

#### **▲**Warning:

- DO NOT use Pentamidine with this device.
- DO NOT use water only in the nebulizer for inhaling purposes.

#### ⚠Caution:

- DO NOT add more than 10 ml of medication to the medication container.
- To prevent damage to the device, add the medication slowly.
   DO NOT allow the medication to overflow the Medication Port.
- Place the mesh cap on the medication container (See right image).





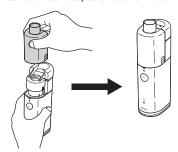


Push the lid of medication container into place until it clicks. Mesh Cap is fixed.

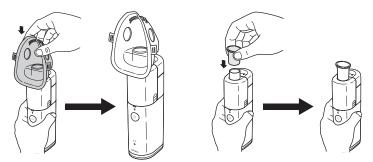
⚠Caution: To prevent damage to the device, make sure that the Mesh Cap is correctly in place. If the Mesh Cap is not properly closed, medication will leak out of the device.



7. Install the mask adapter on the main unit.



8. Install the mask or mouthpiece on the mask adapter.



The device is now ready for use. Refer to sub-section 3.1 for How to Inhale.

#### 3.1 How to Inhale

#### **♠**Warning:

- For type, dose, and regimen of medication follow the instructions of your physician and/or licensed healthcare practitioner.
- ALWAYS dispose of any remaining medication after use. ALWAYS use fresh medication for each treatment.
- This device contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

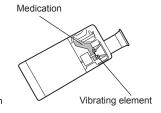
#### **⚠** Caution:

- Inspect the main unit and the parts before each use to ensure that parts are not damaged, the
  device is assembled properly and it is operating normally.
- Do not operate the device at temperatures greater than +104° F (+40° C).
- Slightly tilt the unit as illustrated in the figure.
   In this position, the vibrating element is immersed in the medication and nebulization will start after the device is powered on.

After the vibrating element has been immersed in the medication, the unit can be used at any angle.

#### Notes:

- In some positions, nebulization may stop after a short while, In that case, briefly tilt the unit in order to immerse the vibrating element in the medication.
- If the vibrator is not immersed in the medication, when the ON/OFF Button is pressed:
  - the battery life may be shortened or
  - the Battery Low Indicator may flash
  - the Battery Low Indicator may turn on
  - a metallic noise may be heard, which is normal



Place the mouthpiece in your mouth or place the mask over your mouth and nose.



3. Press the ON/OFF ( $\circlearrowleft$ ) button to start treatment and inhale medication as directed by your physician and/or licensed healthcare practitioner.

The green power indicator lights up during nebulization.

 Press the ON/OFF (<sup>(b)</sup>) button to turn off the device when finished the treatment.

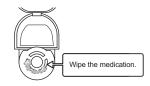
Note: Unplug the power cord from the electrical outlet after using the device.



Note: If high viscosity medication such as Acetylcysteine is used, nebulization may be reduced.

If excessive medication collects on the mesh, nebulization may stop. In that case, turn off the power and remove the mask adapter. Wipe off the medication using a lint-free cloth.

⚠Caution: DO NOT push or poke at the mesh with items such as a cotton swab or pin.



After inhalation always switch off the nebulizer by pressing the ON/OFF (ರ) button.

Note: The device automatically turns off after 30 minutes.

### 3.2 How to Clean the Device After Each Use

The following items should be disassembled and cleaned after each use in order to prevent any remaining medication in the container from drying or adhering to the mesh cap which will result in ineffective nebulization.

Main unit, medication container, mesh cap, mask adapter, mouthpiece and mask.

#### **▲**Warning:

- Failure to properly clean the MICROAir components will result in the risk of bacterial growth, serious illness from contamination, compromised medication delivery.
- Do not leave the cleaning solution on the nebulizer parts. Rinse the nebulizer parts with clean tap water after cleaning.
- Allow the parts to dry after cleaning before reassembling and store in a clean location so that this device will not become contaminated.
- Do not immerse the main unit (except the vibrating element and the area around the vibrating element) and the AC adapter in water or other liquid.
- Remove the mask adapter from the main unit by pressing both sides of the mask adapter.

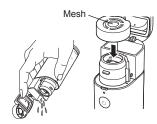


2. Open the medication container and remove the mesh cap.



3. Discard the medication, then re-install the mesh cap.





4. Fill the medication container with water and close the lid of medication container. Nebulize the distilled water for 1 to 2 minutes to prevent medication from drying and adhering to the mesh after use.



Do not inhale water.

Open the lid of medication container and remove the mesh cap from the medication container, then disassemble the medication container from the main unit by rotating counter-clockwise and pulling-up.

Note: Remove the medication container AFTER discarding the medication.





6. Clean the device.

Refer to sub-section 2.2.

#### 3.3 How to Store

- 1. Make sure all cleaned components are completely dry.
- 2. Assemble the device.
- 3. Store the device in Storage Case (see page 30) or in a clean environment.



### 4. Troubleshooting

In case of any of the below problems occur during use, first check that no other electrical device is within 12 inches (30cm).

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

Problem	Possible cause	Solution	
	Batteries are low (the orange battery low indicator flashes).	Replace the batteries with new ones. Refer to sub-section 2.3.	
The nebulization rate is extremely low.	The mesh is stained or clogged.	Clean the mesh. Refer to subsection 2.2.     Replace the mesh cap with a new one. Refer to sub-section 2.5.	
	The batteries are depleted (the orange battery low indicator turns on).	Replace the batteries with new ones or use the AC adapter(Optional). Refer to sub-section 2.3 and 2.4.	
	The capacity of rechargeable batteries is low.	Charge the batteries with a commercially available recharger.	
The green power indicator does not turn	The batteries are inserted in the wrong direction.	Re-insert the batteries in the correct direction. Refer to sub-section 2.3.	
on and the unit does not nebulize.	The AC adapter (Optional) is not connected correctly to a power outlet.	Check that the AC adapter is connected to a power outlet and main unit. Unplug then reinsert the plug if necessary.	
	The contact on the AC adapter (Optional) is contaminated.	Wipe away any contamination with a cloth that has been lightly moistened with water or sanitizing alcohol. Dry completely before use.	

### 4. Troubleshooting

Problem	Possible cause	Solution
	The vibrating element is not immersed in the medication.	Tilt the main unit in order to immerse the vibrating element in the medication.
The green power	The medication container is not filled with medication.	Fill with medication. Refer to subsection 2.5.
indicator turns on but the unit does not	The mesh is broken.	Replace with a new one. Refer to sub-section 2.5.
nebulize.	Excessive medication is collected on the mesh	Remove excessive medication. Refer to page 23. Remove visible liquid with a soft cloth and a very light touch so as not to damage the mesh.
The green power indicator turns on but it nebulizes weakly, or is taking too long for treatment.	Nebulization rates vary based on the medication used.	Treatment times may vary among medications and patients.

If the device does not nebulize properly after checking the possible causes above, contact customer service 1-800-634-4350.

### 5. Maintenance

### 5.1 How to Replace the Mesh Cap

Omron recommends replacing the mesh cap after approximately 1 year (Please refer to section 7 "Durable period").

Remove the mesh cap and install a new one as described on sub-section 2.5.

### 5.2 Carrying Your Device with Storage Case

#### ⚠Caution:

- To prevent damage to the device, DO NOT carry or leave the Medication Container with medication or distilled water.
- DO NOT put the AC Adapter in the Storage Case.
   The Storage Case is not intended to carry the optional AC Adapter.

Assemble the device by attaching the Mesh Cap and Medication Container to the Main Unit. Place the Main Unit Cover on the device.

Position the device in the Storage Case as shown in the illustration.

The Mouthpiece and Mask Adapter can be placed in the Storage Case to carry with the Main Unit.

To carry the AC Adapter bundle the cable of the AC Adapter as shown in the illustration.





### 5. Maintenance

### 5.3 Disposal

Dispose of the device, components and optional accessories according to applicable local regulations.

### 6. Optional Medical Accessories

Product Description	Model
Adult Mask (PVC)	9920
Child Mask (PVC)	9921
Mouthpiece	U22-1
Mask Adapter	U100-2
Medication Container	U100-3
Mesh Cap	U100-4
AC Adapter	U100-5

Product Category: Nebulizers

Product Description: Vibrating Mesh Nebulizer

Model: NE-U100 Rating: 3V === 1.2W

Power Source: 100-240V~ 0.12-0.05A 50-60Hz (Optional AC adapter)

2 "AA" alkaline batteries 1.5V

2 "AA" NiMH rechargeable batteries 1.2V

Operating Mode: Continuous Use Residual Volume: Approx. 0.5 ml Battery Life: Approx. 4 hours

Operating Temperature/ +50°F to +104°F (+10°C to +40°C), 30 to 85%RH (non-

Humidity/Air Pressure: condensing), 800 - 1060hPa

Storage and Transport

Temperature/Humidity: -4°F to +140°F (-20°C to +60°C), 10 to 90%RH (non-condensing)

Weight: \* Approx. 4.2 oz (120g) (excl. batteries)

Dimensions: \*Approx. 1.5" (W) x 5.1" (H) x 2.4" (D) (38mm x 130mm x 60mm)

Contents: Main Unit Cover, Medication Container, Mesh Cap,

Mask Adapter, Mouthpiece, 2 Batteries (AA/LR6), Child Mask (PVC), Storage Case, Instruction Manual

Classifications: Internally powered ME equipment (When using only the batteries)

Class II ME equipment (When using the optional AC adapter)

Type BF (Applied part); Mouthpiece, Mask IP55 (When using only the batteries)

IP22 (When using the optional AC adapter)

<sup>\*</sup> Main Unit assembled with Medication Container and Mask Adapter

#### 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 what is defined in the specifications.

Particle Size: \*MMAD Approx. 5µm

MMAD = Mass Median Aerodynamic Diameter

Medication Container Capacity: 10 ml maximum Sound: Approx. 20 dB

ound: Approx. 20 dB

**Nebulization rate:** \*\*Greater than 0.25 ml/min (by weight loss)

 Aerosol Output:
 0.5 ml (2 ml, 1%NaF)

 Aerosol Output Rate:
 0.1 ml/min (2 ml, 1%NaF)

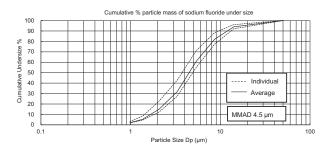
#### Notes:

The distribution of particle size and aerosol output are measured with 2.5% NaF aqueous solution.
 The particle size distribution and aerosol output may vary by combination of product, medication and ambient conditions such as temperature, humidity and atmospheric pressure.

- Performance may vary with the mesh and medication used such as suspensions or high viscosity.
   See medication supplier's data sheet for further details.
- · Treatment time 5 minutes for 2 ml.
- 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.
- With respect to electric shock and mechanical hazards only in accordance with ANSI/AAMI ES60601-1:2005/(R)2012.

	Pulmicort®	Intal <sup>®</sup>	Salbutamol <sup>®</sup>
MMAD (micron)	7.5µ	6.91µ	6.07µ
GSD (geometric standard deviation)	1.81	2.01	1.90
Respirable fraction (%mass 0.52 to 6 µ)	21.2%	28.8%	33.6%

- Measured values reflect internal data obtained by NEXT GENERATION IMPACTOR (NGI), according to EN13544-1:2007 + A1:2009.
- \*\* The Nebulization rate is measured with saline 0.9% solution at 23°C at spray angle of 30° with 3 ml of medication. It can vary with medication and ambient conditions.



#### Durable period

Durable periods are as follows, provided the product is used to nebulize a medication twice 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.

Main Unit	5 years
AC Adapter (optional)	5 years
Medication Container	1 year
Mesh Cap	1 year
Mouthpiece	1 year
Mask (PVC)	1 year
Mask Adapter	1 year

### 8. FCC Statement

#### FCC CAUTION

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

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

#### Note:

This equipment 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. This equipment 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 this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, 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 equipment and receiver.
- Connect the equipment 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.

### 9. Limited Warranty

Your NE-U100 main unit, excluding the Main Unit Cover, Medication Container, Mesh Cap, Mask Adapter, Mouthpiece, Batteries, Child Mask (PVC), and Storage Case is warranted to be free from defects in materials and workmanship appearing within 2 years from the date of purchase, when used in accordance with the instructions provided with the NE-U100.

The above warranty extends only to the original retail purchaser. We will inspect and replace your unit without charge as deemed necessary by the above warranty. This is our only responsibility and your only remedy under the above warranty.

To obtain warranty service contact Customer Service by calling **1-800-634-4350** for the address of the inspection center 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.

#### FOR CUSTOMER SERVICE

Visit our web site at: Call toll free: OmronHealthcare.com 1-800-634-4350

### 10. Guidance and Manufacturer's Declaration

**OMRON Mesh Nebulizer** 

Information for accompanying documents in the scope of IEC60601-1-2:2014

#### Important information regarding Electro Magnetic Compatibility (EMC)

NE-U100 manufactured by OMRON HEALTHCARE Co., Ltd. conforms to IEC60601-1-2:2014 Electro Magnetic Compatibility (EMC) standard.

Further documentation in accordance with this EMC standard is available at OmronHealthcare. com/emc.

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