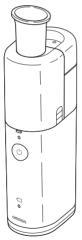
Instruction manual

OMRON



Mesh Nebulizer NE-U100



- English
- Korean
- Chinese



TC

All for Healthcare

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Dear customer,

Thank you for purchasing the OMRON NE-U100 Nebulizer.

By buying the NE-U100 nebulizer, you have chosen a high-quality, innovative device.

During its development, particular attention was given to reliability, easy and convenient handling.

Before using the nebulizer for the first time, please read through this manual carefully.

If you still have any questions regarding its use, contact OMRON customer service at the address shown on the packaging or in this instruction manual. They will be pleased to assist you.

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, or healthcare personnel or patient under the guidance of qualified medical experts. The user should also be capable of understanding general operation of NE-U100 and the content of instruction manual. 			
Intended Patients	This product should not be used by 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, in a room of general household.			
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		
	Medication Container	1 year		
	Mesh Cap	1 year		
	Mouthpiece	1 year		
	Mask (PVC)	1 year		
	Mask Adapter	1 year		
Precautions for use	Warnings and cautions described in the instruction manual should be observed.			

Important Safety Precautions

■ This section provides information about how to use the product safely and to prevent injury to yourself and others as well as property damage.

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

(Usage)

- · For type, dose, and regime of medication, follow the instructions of your doctor or pharmacist.
- If you experience any allergic reactions or other difficulties during use, stop using the device immediately and consult your doctor.
- Keep the device out of reach of unsupervised infants and children.
- · Always dispose of any remaining medication after use, and use fresh medication each time.
- This product should not be used on patients, who are unconscious or are not breathing spontaneously.
- Do not use only water in the nebulizer for inhaling purposes.
- Do not touch the vibrating element while the power is on.
- Do not use the device where it may be exposed to flammable gas.
- Do not use or store the device in a humid location such as a bathroom.
- Do not leave the device or its parts where it will be exposed to extreme temperatures or changes in humidity, such as leaving the device in a vehicle during warm or hot months, or where it will be exposed to direct sunlight.
- Do not use in anaesthetic or ventilator breathing circuits.

(Power source)

- Do not operate the device with a damaged AC adapter.
- Plug the AC adapter into appropriate voltage outlet.
- · Do not use in a multi-outlet plug.
- · Never plug or unplug the AC adapter with wet hands.

(Cleaning and disinfecting)

- Clean and disinfect the product's parts before using the product for the first time, after the product has not been used for an extended period of time and when parts are contaminated.
- · Clean the product's parts after each use and disinfect the product's parts daily during normal use.

EN

Important Safety Precautions

- When the product is being used by different people, clean and disinfect the product's parts after each person's use.
- Follow the disinfectant manufacturer's instructions and make sure there is no disinfectant left on the product after disinfecting it.
- Allow the product's parts to dry after cleaning and disinfecting before reassembling the product and store in a clean location so that the product 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.

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

(Usage)

- Close supervision should be provided by a parent or caregiver when this device is used by, on, or near children or disabled individuals.
- 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 eyes.
- Do not operate the nebulizer with the medication container empty.
- · Approved for human use only.
- Use only OMRON original and optional accessories specified for this device.
- Do not add more than 10 ml of medication to the medication container.
- Do not subject the device to any strong shocks such as dropping on the floor.
- Do not cover the main unit with a blanket, towel, or any other type of cover during use.
- Do not disassemble or attempt to repair the main unit or AC adapter.
- Do not poke the mesh with a cotton swab or a pin.
- 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.

Important Safety Precautions

(Power source)

- Use only the original AC adapter.
- · Fully insert the power plug into the outlet.
- · Wipe the dust off from the power plug.
- · When handling the AC adapter, take care not to do the following:

Do not damage. Do not break it.

Do not tamper with it.
Do not twist.
Do not bundle during use.
Do not pinch.
Do not place under heavy objects.

- Do not use extension cords. Plug the power cord directly into the outlet.
- When disconnecting the power plug from the outlet, do not pull the power cord.
 Be sure to pull from the power plug safely.
- Unplug the product if it will not be used for an extended period of time.
- · Always remove the AC adapter from the device before cleaning.
- 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.

(Cleaning and disinfecting)

- Do not use a microwave oven to boil or dry parts.
- · Do not use a hair dryer to dry parts.
- Do not use a dishwasher to wash or dry parts.
- Do not leave the cleaning solution in the nebulizer parts. Rinse the nebulizer parts with clean tap water after disinfecting.
- Store the device and the components in a clean, safe location.

General Safety Precautions

- Do not use the product for any purpose other than inhalation.
- · Never clean with benzene or thinner.

Keep these instructions for future reference.

Features and benefits

In the NE-U100, aerosol is generated by pushing liquid medication through fine holes in the metal alloy mesh. This is realised by a titanium vibrating element, oscillating at high frequency.

True portable, pocket size

The device will fit in any handbag or briefcase. Running up to approx. 4 hours on just two AA/LR6 batteries, your medication is always within reach wherever you go, whatever you do.

Inhalation is possible at various angles

The device enables inhalation at various angles with stable nebulization. Therefore the device can be used even while in bed or can be used for a baby/child, laying in the arms of the care-taker.

ΕN

Soundless operation

The soundless operation of the device enables discreet use.

No loud frightening noises, meaning calm treatment even while using it on a sleeping child.

Simple one-button operation

Wide medication compliance

Easy to assemble, simple preparation

Contents of the OMRON NE-U100 package

The following items are contained in the package:

Main Unit Cover



Main Unit



Medication Container



Mesh Cap



Mask Adapter



Mouthpiece



Batteries (2x AA/LR6)



- · Instruction Manual
- Quick Setup Guide

Child Mask (PVC)







Soft Pouch



Names and functions of the parts

Mesh Cap

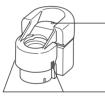
Contains metal alloy mesh for nebulization.



Mesh

Nebulized medication exits here through minute pores.

Medication container



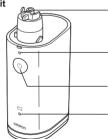
Air opening

Stabilizes nebulization.

Medication container lid release button

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

Main unit



Vibrating element

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.

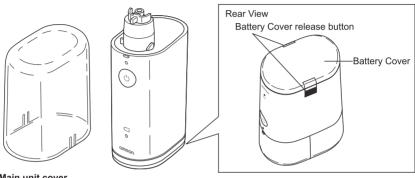
ON/OFF (也) button

Battery Low Indicator

An orange light blinks when the batteries are low.

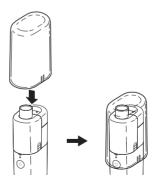
EN

Names and functions of the parts



Main unit cover

Protects the Main Unit with the attached Medication Container and Mesh Cap during storage.

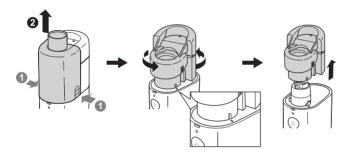


Before using the product for the first time

Before first use: I) Carefully read the Instruction Manual

II) Disassemble, clean and disinfect the parts

Disassembly

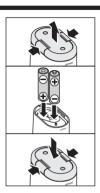


EN

How to insert or replace the batteries

Inserting batteries

- 1. Remove the battery cover on bottom side by pushing on the release buttons on both sides.
- 2. Insert the batteries according to the battery polarity indicated inside the battery compartment.
- 3. Replace battery cover by pushing 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.



- The battery low indicator will turn off if no button is pressed for 10 seconds or if you turn off the device.
- · Remove batteries if the unit is not in use for long periods. Failure to do so could result in damage due to battery leakage.
- · Batteries should be treated as chemical waste; disposal should be done at your retail store or at appropriate collection locations.

ΕN

Using the AC adapter (Optional)

⚠Caution: Use only the original AC adapter as indicated in section "Optional Medical Accessories" on page 24.

Note: There is no optional AC adapter in Taiwan.

To connect the AC adapter to the main unit

- (1) Remove the battery cover and remove the batteries, see page 12.
- (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.

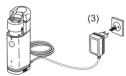
⚠ Caution: Never plug or unplug the AC adapter with wet hands.

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

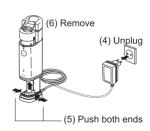
To remove the AC adapter from the main unit

- (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.





Connection is completed.

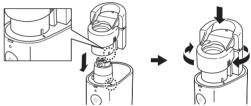


How to assemble the unit and fill the medication container

⚠ Caution:

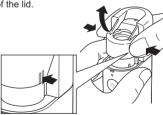
Clean and disinfect the product's parts before using the product for the first time, after the product has not been used for an extended period of time and when parts are contaminated. (Refer to page 19 for instructions.)

- 1. Insert batteries, see page 12.
- 2. 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.

3. Open the medication container by pressing on both sides of the lid.



How to assemble the unit and fill the medication container

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



5. Place the mesh cap.



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

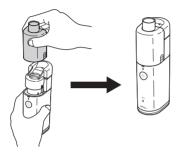




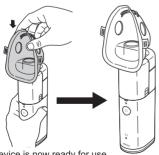
ΕN

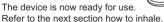
How to assemble the unit and fill the medication container

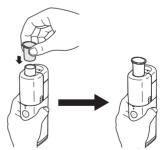
7. Install the mask adapter on the main unit.



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







How to inhale with the OMRON NE-U100

⚠Caution: For type, dose, and regime of medication, follow the instructions of your doctor or pharmacist.

1. 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 power on.

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

Note: In some positions (e.g. upright), nebulization may stop after a short while. In that case, briefly tilt the unit again in order to re-immerse the vibrating element in the medication.

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



Medication

3. If you push the ON/OFF (Φ) button, nebulization starts. If you push the ON/OFF (Φ) button again, nebulization stops.

The green power indicator lights up during nebulization.

Always be calm and relaxed when you inhale. Breathe in slowly and deeply so that the medication can reach deep into the lungs. Hold your breath briefly, then breathe out slowly while removing the mouthpiece from your mouth. Do not breathe too quickly. Pause when you feel like having a rest.



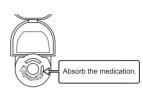
Vibrating element EN

How to inhale with the OMRON NE-U100

Note: If high-viscosity medication 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. Absorb the medication by means of a lint-free cloth.

Note: Do not poke the mesh with a cotton swab or a pin; the mesh may be permanently damaged.



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

Note: The device automatically turns off after 30 minutes.

How to clean the unit after each inhalation

The following items should be disassembled and cleaned after each use: Medication container, mesh cap, mask adapter, mouthpiece and mask.

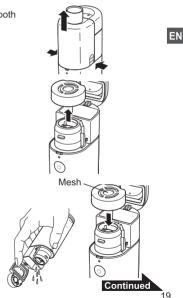
Note: if the device is not cleaned and disinfected correctly and frequently, micro-organisms may remain in the unit, causing risk of infection.

1. 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.



How to clean the unit after each inhalation

4. Fill the medication container with water and nebulize the water. To prevent medication from drying and adhering to the mesh after use, nebulize the water for 1 to 2 minutes.



Do not inhale water.

5. 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. Follow the below instructions to clean all parts.

Mesh Cap

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

Some types of medications can easily remain on the mesh, therefore pay close attention during washing. Do not wash under running water.





ΕN

Medication Container, Mouthpiece, Mask and Mask adapter

Wash them in water and mild (neutral) detergent. Rinse them thoroughly with clean tap water and allow to air dry in a clean place.



Vibrating element and its surrounding

Wash with running water.

Note: Make sure the battery cover is installed to prevent liquid entering the device.



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.



How to disinfect the parts

Note: if the device is not cleaned and disinfected correctly and as frequently as indicated, microorganisms may remain in the unit, causing risk of infection.

The Medication Container, Mesh Cap, Mouthpiece, Mask and Mask Adapter should be disinfected before using the unit for the first time, after the unit has not been used for a long period of time, or daily during normal use.

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

Parts		Materials	Boiling	Alcohol	Sodium hypochlorite	Quaternary ammonium	Chlorhexidine	Amphoteric surfactant
				Disinfecting ethanol	Milton*1 (0.1%)	Osvan*1 (0.1%)	Hibitane*1 (0.5%)	Tego*1 (0.2%)
Mouthpiece		SEBS	0	0	0	0	0	0
Mask Adapter	Ø)	PC	0	0	0	0	0	0
Medication Container		Body: PC Hinges: Titanium	0	0	0	0	0	0
Mesh Cap	©	Packing: Silicone Mesh Holder: PC Mesh: NiPd		0	×	0	0	0
Adult Mask (PVC) Child Mask (PVC)		Mask: PVC*3 Band: Rubber*4	×	O*2	O*2	O*2	O*2	O*2
Vibrating element		Titanium	×	0	0	0	0	0

O: applicable x: not applicable

How to disinfect the parts

■ Disinfection by commercially available disinfectant

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

Note: Never clean with benzene or thinner.

· Vibrating element and its surrounding

Soak the vibrating element and the area around the vibrating element in disinfectant.

 Medication Container, Mouthpiece, Mesh Cap, Mask Adapter and Mask Soak the parts in disinfectant.

■ Disinfection by boiling

• Medication Container, Mouthpiece, Mesh Cap and Mask Adapter 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.



- *1 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.)
- *2 Remove the rubber band from mask before disinfecting.
- *3 The mask is phthalate free.
- *4 The band is not made with natural rubber latex.

How to replace the mesh cap

The mesh cap is a consumable part.

OMRON recommends to exchange the mesh cap after approximately 1 year (Please refer to page 3 "Durable period").

Remove the mesh cap and install a new one as described on page 14 (section "How to assemble the unit and fill the medication container").

Optional Medical Accessories

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

Product description	Model
Adult Mask (PVC)	NEB-MSLP-AP
Child Mask (PVC)	NEB-MSMP-AP
Mesh Cap	NEB-MC-10E
Medication Container	NEB-BTL-10E
Mask Adapter	NEB-MSA-10E
Mouthpiece	U22-1-E
AC Adapter	NEB-AC-10AP

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.

Trouble	Possible cause	Corrective action
	Batteries are low (the orange battery low indicator flashes).	Replace the batteries with new ones. Refer to page 12.
The nebulization rate is extremely low.	The mesh is stained or clogged.	Clean the mesh by boiling. Refer to page 22. Replace the mesh cap with a new one. Refer to page 14.
	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 page 12 or 13.
The green power indicator does not turn on and the unit does not nebulize.	The capacity of rechargeable batteries is low.	Charge the batteries with a commercially available recharger.
	The batteries are inserted in the wrong direction.	Re-insert the batteries in the correct direction. Refer to page 12.
	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 moistened with water or sanitizing alcohol and then wrung out lightly.

Troubleshooting

Trouble	Possible cause	Corrective action		
The green power	The vibrating element is not immersed in the medication.	Tilt the main unit in order to immerse the vibrating element in the medication.		
	The medication container is not filled with medication.	Fill with medication. Refer to page 14.		
indicator turns on but the unit does not	The mesh is broken.	Replace with a new one. Refer to page 14.		
nebulize.	Excessive medication is collected on the mesh	Remove excessive medication. Refer to page 18. 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 unit does not nebulize properly after checking the possible causes above, contact your OMRON customer service.

ΕN

Technical data

Product Category: Nebulizers
Product Description: Mesh Nebulizer
Model: NF-IJ100

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

3 VDC (two batteries/Type AA/LR6)

Power Consumption: Approx. 1.2 W
Residual Volume: Approx. 0.5 ml
Battery Life: Approx. 4 hours

Operating Temperature/

Humidity/Air Pressure: Storage and Transport

Weight:

+10°C to +40°C, 30 to 85%RH (non-condensing), 800 - 1060hPa

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

* Approx. 120g (excl. batteries)

Dimensions: * Approx. 38 (W) x 130 (H) x 60 (D) mm

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

Mask Adapter, Mouthpiece, 2 Batteries (AA/LR6), Adult Mask (PVC), Child Mask (PVC), Soft Pouch, Instruction Manual, Quick Setup Guide

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)

IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. The device is protected against ingress of dust which would cause issues during a normal operation and against water jets which may cause issues during a normal operation. The optional AC adapter is protected against solid foreign objects of 12.5mm diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation.

^{*} Main Unit assembled with Medication Container and Mask Adapter

Technical data

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.
- If the device is stored at the maximum or minimum storage and transport temperature and is moved to an environment with a temperature of 20°C, we recommend waiting for approx. 1 hour before using the device.
- This device complies with the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN13544-1:2007, Respiratory therapy equipment - Part1: Nebulizing systems and their components.

C € 0197

Symbols description

[]i	Need for the user to consult the instructions for use	1	Temperature limitation
†	Applied part - Type BF Degree of protection against electric shock (leakage current) Humidity limitation		Humidity limitation
	Class II Protection against electric shock	9	Atmospheric pressure limitation
IPXX	IPXX Ingress protection degree provided by IEC 60529		Power ON / OFF
C€	CE Marking	\sim	Alternating current
SN Serial number			Direct current

Technical data

Particle Size: *MMAD 4.5 um

MMAD = Mass Median Aerodynamic Diameter

Medication Container Capacity: 10 ml maximum Sound:

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)

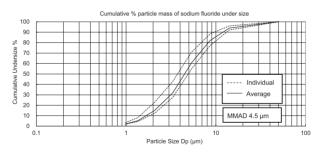
Notes:

• 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.

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

** 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.



Technical data

Important information regarding Electro Magnetic Compatibility (EMC)

NE-U100 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-U100 on the web site.

Refer to the EMC information for NE-0 100 on the web sit

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 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 take 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.

Memo

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EU-representative EC REP	OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com
Production facility	OMRON HEALTHCARE Co., Ltd. Matsusaka Factory 1855-370, Kubo-cho, Matsusaka-shi, Mie, 515-8503 Japan
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Made in Japan